In The

Supreme Court of the United States

ROSA PÉREZ-PERDOMO, in her official capacity as Secretary of Health of the Commonwealth of Puerto Rico,

Petitioner,

v.

WALGREEN CO.; WALGREEN OF SAN PATRICIO; and WALGREEN OF PUERTO RICO,

Respondents.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The First Circuit

PETITION FOR WRIT OF CERTIORARI

MIGUEL A. SANTANA-BAGUR
Deputy Attorney General
of Puerto Rico
Counsel of Record

SALVADOR J. ANTONETTI-STUTTS
Solicitor General of Puerto Rico

MARIANA D. NEGRÓN-VARGAS
Deputy Solicitor General

MAITE ORONOZ-RODRÍGUEZ
Deputy Solicitor General

DORALIZ E. ORTIZ-DE-LEÓN
Assistant Solicitor General
Department of Justice
P.O. Box 9020192
San Juan, Puerto Rico 00902-0192
Tel. (787) 724-2165 Ext. 2707
Fax (787) 724-3380

COCKLE LAW BRIEF PRINTING CO. (800) 225-6964
OR CALL COLLECT (402) 342-2831

QUESTIONS PRESENTED

The National Health Planning and Resources Development Act of 1974, Pub. L. No. 93-641, 88 Stat. 2225 (repealed 1986) (the "1974 Act"), expressly conditioned the receipt of federal health care funds by the States on their establishment of "Certificate of Need" ("CON") programs. Relying on the federal statute, the Commonwealth of Puerto Rico and forty-nine of the States enacted legislation creating CON programs, which require health service providers to demonstrate that there is a need for their services in a particular locale before they engage in certain regulated activities. In 1979, the Commonwealth of Puerto Rico included pharmacies within the scope of its CON program. Although Congress repealed the 1974 Act in 1986, it did not require the States to repeal their own CON laws. Accordingly, these laws continue to be enforced, not only in Puerto Rico, but also in approximately 37 States. The U.S. Court of Appeals for the First Circuit, however, held that Puerto Rico's CON statute, at least as applied to pharmacies, violates the dormant Commerce Clause.

The questions presented are:

1) Whether the fact that the National Health Planning and Resources Development Act of 1974 clearly authorized State CON laws continues to insulate such laws from dormant Commerce Clause scrutiny, even though the Act was repealed in 1986; and

2) If the answer to Question 1 is no, then whether a CON program runs afoul of the dormant Commerce Clause, even if it is facially-neutral with

QUESTIONS PRESENTED – Continued

respect to interstate commerce, and even if the incidental effects it has on interstate commerce were the result of the incorporation of a grandfather clause intended to avoid the potential for unfairness in retroactively applying the new requirements to existing health-care institutions.

PARTIES TO THE PROCEEDINGS

The appellants below were Walgreen Co., Walgreen of San Patricio, Inc., and Walgreen of Puerto Rico, Inc. The appellee was John V. Rullán in his official capacity as Secretary of Health of the Commonwealth of Puerto Rico. Thereafter Rosa Pérez-Perdomo substituted John V. Rullán as Secretary of Health, and is the petitioner in this proceeding pursuant to Sup. Ct. R. 35.3.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page

CASES

TABLE OF AUTHORITIES – Continued

TABLE OF AUTHORITIES – Continued

TABLE OF AUTHORITIES – Continued

LAW REVIEW ARTICLES

TABLE OF AUTHORITIES – Continued

OPINIONS BELOW

The opinion of the United States Court of Appeals for the First Circuit reversing the District Court's judgment was entered on April 22, 2005, is reported at *Walgreen Co. v. Rullán,* 405 F.3d 50 (1st Cir. 2005), and is reproduced in the appendix at 1-19. The order of the Court of Appeals denying the petition for rehearing en banc was entered on June 7, 2004, is not officially reported, and is reproduced in the appendix at 52-53. The opinion of the District Court granting Petitioner's motion for summary judgment was entered on September 8, 2003, is reported at *Walgreen v. Rullán,* 292 F. Supp. 2d 298 (D.P.R. 2003), and is reproduced in the appendix at 20-51.

STATEMENT OF JURISDICTION

The decision of the Court of Appeals was entered on April 22, 2005. App. 2. A timely petition for rehearing en banc was denied on June 7, 2005. App. 52. On August 24, 2005, this Honorable Court granted an extension of time until November 4, 2005, to file the instant petition. The jurisdiction of this Court is invoked pursuant to 28 U.S.C. § 1254(1).

CONSTITUTIONAL PROVISIONS, STATUTES AND REGULATIONS INVOLVED IN THE CASE

1. The Commerce Clause of the United States Constitution, which grants Congress the power: "[t]o regulate commerce with foreign nations, and among the several States, and with the Indian tribes." U.S. Const. Art. I, § 8, cl. 3.

2. The Certificate of Necessity and Convenience Act of the Commonwealth of Puerto Rico (hereinafter "the CNC Act"), 1975 P.R. Laws 2 (codified as amended at 24 P.R. Laws Ann. §§ 334-334j), reproduced in the appendix to the petition at 54-74.

3. Puerto Rico Department of Health Regulation No. 3335 of August 15, 1986 (hereinafter "Regulation 56"), *repealed by* Regulation No. 6786 of March 9, 2004 (hereinafter "Regulation 112"). The official translation of Regulation 56 is reproduced in the appendix to the petition at 75. The certified translation of Regulation 112 is reproduced in the appendix to the petition at 126.

STATEMENT OF THE CASE

A. Statutory Background

As noted earlier, Congress enacted the National Health Planning and Resources Development Act of 1974 as a means to promote the orderly planning of health services by the states and thus correct perceived deficiencies in the existing health system. *See* Pub. L. No. 93-641, 88 Stat. 2225 (repealed 1986). It found that the lack of uniformity within the system prompted an unnecessary duplication of health services and contributed to an inflationary increase in health costs. Additionally, the uneven distribution of resources left large segments of the population lacking even the most basic knowledge about proper health care and the effective use of available services. *Id.* In order to correct these deficiencies, Congress conditioned the receipt of federal health care funds by the states to the establishment of CON programs, which require health service providers to demonstrate that

there is a need for their services before they engage in certain regulated activities.

Accepting the invitation extended by Congress, forty-nine States and the Commonwealth of Puerto Rico adopted such laws. Although the Act was repealed in 1986, the State CON laws remain in effect and are still enforced in about 37 States and the Commonwealth.[1]

Puerto Rico's CNC Act, which was adopted on November 7, 1975, provides that those interested in establishing health facilities must first obtain certificates of necessity and convenience from the Secretary of Health. 24 P.R.

---

[1] *See, eg.*, Ala. Code §§ 22-21-260 *et seq.*; Alaska Stat. §§ 18.07 *et seq.*; Con. Gen. Stat. §§ 19a-637 *et seq.*; D.C. Code Ann. §§ 44-401 – 44-402; Fla. Stat. Ann. §§ 408.031 – 408.045; Ga. Code Ann. §§ 31-6-1 *et seq.*; Haw. Rev. Stat. §§ 323D-43 *et seq.*; Ill. Comp. Stat. §§ 3960/1 *et seq.*; Iowa Code Ann. §§ 135.61 *et seq.*; Ky. Rev. Stat. Ann. §§ 216B.010 *et seq.*; La. Rev. Stat. Ann. § 40:2116; Md. Code Ann. [Health General I] §§ 19-114 *et seq.*; Mass. Gen. Laws Ann. ch. 111 §§ 25B-25H; Me. Rev. Stat. Ann. tit. 22 §§ 326 *et seq.*; Mich. Comp. Laws. Ann. §§ 333.22201 *et seq.*; Miss. Code Ann. §§ 41-7-171 *et seq.*; Mo. Ann. Stat. § 197.315; Mont. Code Ann. §§ 50-5-301 – 50-5-309; Neb. Rev. Stat. §§ 71-5801 – 71-5870; Nev. Rev. Stat. §§ 439A.010 – 439A.0195; N.J. Stat. Ann. §§ 26:2H-1 *et seq.*; N.H. Rev. Stat. Ann. § 151-C:4; N.Y. Comp. Codes R. & Regs. tit. 10 §§ 709.1 *et seq.*; N.C. Gen. Stat. §§ 131E-175 *et seq.*; Ohio Rev. Code. Ann. §§ 3702 *et seq.*; Okla. Stat. Ann. tit. 63 §§ 1-851 *et seq.*; Or. Rev. Stat. §§ 441 – 442; Pa. Cons. Stat. Ann. §§ 448.103 *et seq.*; R.I. Gen. Laws §§ 23-15-1 *et seq.*; S.C. Code Ann. §§ 44-7-120 *et seq.*; Tenn. Code Ann. §§ 68-11-1601 *et seq.*; Vt. Stat. Ann. tit. 18 §§ 9434 *et seq.*; Va. Code Ann. §§ 32.1-102.1 *et seq.*; 19 V.I. Code Ann. §§ 221 *et seq.*; Wash. Rev. Code. Ann. §§ 70.38.115 *et seq.*; W. Va. Code. §§ 16-2D-1 *et seq.* The American Health Planning Association's web site lists the states that currently have CON laws and provides a detailed description of each of their programs. *See* http://www.ahpanet.org/Con_issues.html. *See also* U.S. General Accounting Office, GAO-04-167, *Specialty Hospitals, Geographic Locations, Services Provided and Financial Performance*, 3-4 (2003) (Report to Congressional Requesters), at http://www.gao.gov/new.items/d04167.pdf.

Laws Ann. § 334a, App. 59. The statute established the general guidelines for granting a certificate, and authorized the Secretary of Health to adopt additional criteria by regulation. *Id.* at §§ 334b-334j, App. 61-74. Pursuant to this grant of authority, the Secretary adopted Regulation 56 on August 15, 1986 (App. 75), which was replaced by Regulation 112 effective April 9, 2004 (App. 126).[2]

On July 26, 1979, the CNC Act was amended to include pharmacies within the definition of "health facilities" covered by the statute. *See* P.R. Laws Ann. § 334(d), App. 54. It also incorporated a grandfather clause that entitled all pharmacies established before October 24, 1979, to automatically receive a certificate of necessity and convenience. *Id.* at § 334g, App. 71. Indeed, the twelve (12) pharmacies that Walgreen had already established in Puerto Rico by that time benefited from this exemption.

A party interested in obtaining a certificate of necessity must first notify the Secretary in writing of its intentions and submit the corresponding petition. *Id.* at § 334f-3, App. 65. The agency is then required to publish a notice of the petition on a newspaper of general circulation, and to notify the persons within the area of the proposed location. *Id.* at § 334f-6, App. 66. With respect to pharmacies, only

---

[2] The Court of Appeals invalidated the CNC Act pursuant to Regulation 56 on April 22, 2005. App. 1. By that time, however, the Department of Health had already replaced Regulation 56 with Regulation 112 (effective April 9, 2004). App. 126. Regulation 112 further liberalized the requirements for a certificate of necessity in favor of both in- and out-of-Commonwealth petitions, in order to accommodate the recent privatization of most health services in Puerto Rico and the accompanying increase in demand for these services. *Compare* App. 99 *with* App. 162. It also liberalized the term of effectiveness of a certificate of necessity. *Compare* App. 118 *with* App. 173.

those located *within a one (1) mile radius* of the proposed location may oppose to the issuance of the certificate, and they must do so within fifteen (15) days of the date of the notice. Art. V § 5 of Regulation 112, App. 145. If an affected person opposes the petition and so requests, the Secretary must afford him or her the opportunity to be heard through an administrative hearing. 24 P.R. Laws Ann. § 334f-7, App. 67-68.

In order to evaluate the CNC petition, the Secretary must take into account the "present and projected need of the population" affected by the transaction, and the existence of alternatives to the transaction or "the possibility of providing the proposed services in a more efficient or less costly manner." *Id.* at § 334b. Additionally, the Secretary must consider the criteria established by regulation, including whether the proposed pharmacy will benefit certain "unattended populations" (*i.e.*, low-income, disabled, or elderly populations) and whether the proposed pharmacy will be located in an area that is already "saturated" by existing pharmacies. *See* Art. VI of Regulation 56 at App. 99, and Art. VII § I of Regulation 112 at App. 162. After the Secretary rules on the petition, the losing party may request reconsideration of the administrative ruling, and may also seek judicial review in the Puerto Rico Circuit Court of Appeals and the Puerto Rico Supreme Court. *See* 24 P.R. Laws Ann. § 334f-10. *Id.*

B. Proceedings Below

1. U.S. District Court for the District of Puerto Rico

On February 24, 2004, Walgreen filed suit against the Secretary of Health pursuant to 42 U.S.C. § 1983, seeking

injunctive and declaratory relief against the enforcement of the CNC Act as applied to pharmacies. Walgreen claimed that the CNC Act infringes the dormant Commerce Clause,[3] the Equal Protection Clause, and the Due Process Clause of the United States Constitution.

Faced with cross motions for summary judgment, the District Court entered a judgment in favor of the Secretary on September 8, 2003. *See Walgreen*, 292 F. Supp. 2d at 298, App. 20. The court concluded that the application of the CNC Act to pharmacies does *not* violate the Due Process Clause or the dormant Commerce Clause.

With respect to the substantive due process claim, the court found that the CNC Act is socio-economic legislation, applied the rational basis test, and upheld the constitutionality of the statute, finding that the Secretary had "established that a rational relationship between the application of the CNC Act to pharmacies and the goal of encouraging the establishment of pharmacies in 'underserved' areas." *Id.* at 310, App. 29-36.

With respect to the dormant Commerce Clause claim, the District Court first found that the CNC Act does not violate the Commerce Clause on its face because it "does not deprive out-of-state businesses of access to the local market ... nor are its economic effects interstate in reach." *Id.* at 313, App. 41. According to the court: "[t]he record contains no hint that the statute is shaped to favor

---

[3] Petitioner questions the underlying basis for Walgreen's claim: that it is, in fact, an out-of-Commonwealth pharmacy. Note that appellants Walgreen of Puerto Rico and Walgreen of San Patricio are both incorporated in Puerto Rico, which should have deprived them of standing to challenge the CNC Act under the dormant Commerce Clause.

local pharmacies. . . . Both in-state and out-of-state applicants may apply freely to obtain a CNC, and national pharmacy chains are not reviewed any differently than local pharmacies." *Id.*, App. 43.

Second, the District Court found that the CNC Act does not have a discriminatory purpose or intent against interstate commerce. *Id.* 314-315, App. 43-44. The statute does *not* distinguish between local pharmacies and out-of-Commonwealth pharmacies, and the grandfather clause does not lead to an inference of discriminatory intent, especially given that Walgreen also benefited from the exemption. *See id.* at 315, App. 44.

Third, the District Court held that the CNC Act does not have a discriminatory effect on interstate commerce. *Id.* at 316, App. 46. The court found that the evidence on the record was insufficient for discerning a pattern of discrimination that amounted to a constitutional violation. *Id.*[4]

---

[4] As stated previously, only those persons located *within a one (1) mile radius* of the proposed location may oppose to a CNC petition, and they must do so within a term of fifteen (15) days from the date of the notice. *See* Art. V § 5 of Regulation 112, App. 145. The record shows that the Secretary rejected only one (1) out of 337 unopposed petitions, and that 23% of opposed petitions have been denied. *Walgreen*, 405 F.3d 56 n.3, App. 11. It also shows that the Secretary issued certificates of necessity to 90% of the local applicants and to 58% of the out-of-Commonwealth applicants. *Id.* at 315, App. 45. While the District Court interpreted this latter statistical difference as indicating only that the approval rate depended on whether applications had been opposed, and not on the identity of the applicants, the Court of Appeals relied on the same evidence to reach the contrary conclusion. *Id.*

Finally, using the balancing test announced in *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970), the District Court held that the CNC Act's modest burden on interstate commerce is *not* clearly excessive in relation to its putative local benefits. *Walgreen,* 292 F. Supp. 2d at 318, App. 50. The statute does *not* prevent out-of-Commonwealth interests from operating in Puerto Rico, and it "applies equally to all potential pharmacies regardless of their point of origin." *Id.* at 317, App. 50. The court found that "Walgreens has not been denied access to the Puerto Rico market, except insofar as it seeks to establish new pharmacies in a one-mile radius where there are other existing pharmacies." *Id.* In fact, the record shows that, at the time of the proceedings below, there were around fifty (50) Walgreen pharmacies operating in Puerto Rico, and that forty-three (43) out of the fifty-eight (58) CNC petitions filed by Walgreen had been granted.[6] *Id.*, App. 49.

2. U.S. Court of Appeals for the First Circuit

Walgreen appealed the District Court's grant of summary judgment in favor of the Secretary of Health, and the First Circuit reversed on April 22, 2005. *Walgreen*, 405 F.3d at 50, App. 1. The Court of Appeals agreed with the District Court that, on its face, the CNC Act applies neutrally to both in- and out-of-Commonwealth interests. *Id.* at 55, App. 9. Nevertheless, without determining

---

[6] The number of Walgreen pharmacies established in Puerto Rico has certainly increased since the time of the proceedings before the District Court. There are currently about sixty-three (63) Walgreen pharmacies operating in the Commonwealth, a number that is surpassed in only seventeen (17) states, all of which have larger populations than Puerto Rico.

whether the District Court's finding of insufficient evidence was clearly erroneous, the Court of Appeals did not merely vacate, but instead reversed the District Court's judgment, holding that the CNC Act violates the dormant Commerce Clause.

The Court of Appeals concluded that the CNC Act has a discriminatory effect on interstate commerce because it has a grandfather clause that exempted *all* pharmacies established before October 1979 from obtaining a certificate of convenience, and over ninety-two percent of those pharmacies were locally owned at the time of the exemption. *Id.* at 55-56, App. 10. The court also concluded that the Secretary's enforcement of the CNC Act is discriminatory, because it allows pharmacies located within a one (1) mile radius of the proposed location to oppose the petition and trigger the administrative hearing process to determine whether a particular area is already saturated with pharmacies. *Id.* at 56-57, App. 10-13. Finally, the Court of Appeals held that, although the Commonwealth indisputably has a legitimate interest in encouraging pharmacies to locate in underserved sectors of the Island, the CNC Act is not reasonably designed to advance that interest. *Id.* at 61, App. 18-19. In its analysis, the Court of Appeals did not give any weight whatsoever to the fact that the CNC Act had been adopted in accordance with the provisions of the National Health Planning and Resources Development Act of 1974.

REASONS FOR GRANTING THE WRIT

The instant case involves two questions of federal law that should be settled by this Court. The first is whether

the repeal of a Congressional act that encouraged states to adopt certain legislation that might otherwise be subject to dormant Commerce Clause scrutiny renders such state statutes vulnerable to dormant Commerce Clause challenges.

Congress can allow States to act in ways that would violate the dormant Commerce Clause. "It is . . . clear that Congress may 'redefine the distribution of power over interstate commerce' by 'permit[ting] the states to regulate the commerce in a manner which would otherwise not be permissible.'" *South-Central Timber Development, Inc. v. Wunnicke*, 467 U.S. 82, 87-88 (1984) (quoting *Southern Pacific Co. v. Arizona*, 325 U.S. 761, 769 (1945)).

The key, therefore, is determining whether Congress has, in fact, given its authorization.

Although one possibility was to hold that only express authorization by Congress would pass muster, this Court has consistently rejected such an approach, stating that "[t]here is no talismanic significance to the phrase 'expressly stated' . . . ; it merely states one way of meeting the requirement that for a state regulation to be removed from the reach of the dormant Commerce Clause, congressional intent must be unmistakably clear." *Wunnicke*, 467 U.S. at 91. The Court thus settled on "[a] rule requiring a clear expression of approval by Congress," *id.* at 92; that is, on a "requirement that Congress affirmatively contemplate otherwise invalid state legislation." *Id.* at 91. Accordingly, the statutory text or history claimed to establish consent must "evince[] a congressional intent to alter the limits of state power otherwise imposed by the Commerce Clause." *New England Power Co. v. New Hampshire*, 455 U.S. 331, 341 (1982).

The National Health Planning and Resources Development Act of 1974 was a clear expression of approval by Congress of State CON laws – indeed, it *required* States to adopt CON laws as a prerequisite to receiving certain federal funds.

The difficulty here lies in this: because the 1974 Act was repealed in 1986, does it *still* insulate State CON laws from dormant Commerce Clause scrutiny?

The Court of Appeals has effectively answered no, by scrutinizing the Commonwealth's CNC Act under the dormant Commerce Clause, as well as by holding that the Puerto Rico CNC Act discriminates against interstate commerce. The First Circuit's holding puts in jeopardy governmental efforts by at least thirty-seven states that, like Puerto Rico, currently enforce CON statutes that were originally enacted to comply with the 1974 Act.[6]

---

[6] The national impact of the Court of Appeals' decision is not lessened by the fact that Puerto Rico's CNC Act includes pharmacies in its definition of health facilities. The reasoni used by the Court of Appeals for invalidating the CNC Act is equally applicable to *all* CON programs nationwide, regardless of the type of health facility that they regulate. This is especially true in light of the Court of Appeals' failure to address the propriety of the CNC Act's classification of pharmacies within the definition of health care facilities. In any case, it is clear that the 1974 Act's approval of State CON programs encompassed the Commonwealth's inclusion in its CON program of pharmacies in its definition of "health facilities," since Section 1531(4) of the 1974 Act broadly defined the "health resources" to "include[] health services, health professions personnel, and health facilities," and Section 1531(3)(b)(iii) defined the term "provider of health care" to include pharmacists. "[P]rovider of health care" means "an individual . . . who is an indirect provider of health care in that the individual . . . receives (either directly or through his spouse) more than one-tenth of his gross annual income from . . . producing or supplying drugs or other articles

(Continued on following page)

But the answer to the question whether the 1986 repeal of the 1974 Act deprived state CON laws of their immunity to dormant Commerce Clause challenges depends on what Congress can be understood to have intended by its actions in 1986. Unfortunately, the legislative history of the statute by which the 1986 repeal was effected lacks any explanation; notably, there is no indication that Congress now considered State CON laws to be invalid.

The Commonwealth contends that in cases such as this one, where a federal statute that clearly encouraged a particular kind of state legislation was later repealed, without expressly disavowing the state statutes it earlier encouraged, the Court should still deem the state statutes to be shielded from dormant Commerce Clause scrutiny. After all, the dormant Commerce Clause doctrine is intended to supply a default rule in the absence of guidance by Congress. Here, such guidance was given once, and although the statute that gave it was repealed, Congress remained silent on the key issue of what would happen with state CON laws. Having had the opportunity to speak to the issue, and turned it down, the only reasonable way to interpret what Congress intended is to conclude that it did not wish to change its earlier authorization of such laws.

Admittedly, this Court's precedents do not appear to address this issue squarely – which is precisely the main

---

for individuals or entities for use in the provision of . . . health care." P.L. 93-641, § 1531(3)(b)(iii).

reason why this petition for a writ of certiorari should be granted.

The other reason for issuing the writ in this case is that the invalidation of the CNC Act under the dormant Commerce Clause misapplies the relevant precedents. This Court has long recognized that "[t]he limitation imposed by the Commerce Clause on state regulatory power is by no means absolute, and the States retain authority under their general police powers to regulate matters of legitimate local concern, even though interstate commerce may be affected." *Maine v. Taylor*, 477 U.S. 131, 137-38 (1986) (internal citations omitted). For example, in *Panhandle E. Pipe Co. v. Michigan Pub. Serv. Comm'n*, 341 U.S. 329 (1951), this Court validated a certificate of need law even when it effectively restricted competition. As the Court explained, "[i]t does not follow that because appellant is engaged in interstate commerce it is free from state regulation or free to manage essentially local aspects of its business as it pleases. The course of this Court's decisions recognizes no such license." 341 U.S. at 337 (citations omitted). Likewise, in *Exxon Corp. v. Governor of Md.*, 437 U.S. 117 (1978), this Court explained that "interstate commerce is not subjected to an impermissible burden simply because an otherwise valid regulation causes some business to shift from one interstate supplier to another." *Id.* at 127. The Commerce Clause "protects the interstate market, not particular interstate firms, from prohibitive or burdensome regulations." *Id.* at 127-128.

The Court of Appeals' misapplication of the dormant Commerce Clause doctrine, rather than promoting economic efficiency or national unity, suggests a return to

Lochner-style assumptions about the natural and proper role of state governments in regulating markets.[7] *See Lochner v. New York*, 198 U.S. 45 (1905) (overruled by *Day-Bright Lightning, Inc. v. State of Mo.*, 342 U.S. 421, 423 (1952) ("[o]ur recent decisions make plain that we do not sit as a super-legislature to weigh the wisdom of legislation nor to decide whether the policy which it expresses offends the public welfare."). *See also C & A Carbone, Inc. v. Clarkstown*, 511 U.S. 383, 417 n.6 (1994) (Souter, J., dissenting) ("[t]he negative implications of the commerce clause derive principally from a political theory of union, *not from an economic theory of free trade*" (emphasis added)).

In sum, this Court should issue the writ of certiorari, both because the Court of Appeals' ruling misreads the intent of Congress, and because it misapplies this Court's precedents, thus making CON programs across the nation vulnerable to dormant Commerce Clause challenges.

---

[7] Examples of the Court of Appeals' free-market preferences are not lacking in the opinion. According to the Court, "the certificate requirement *cannot reasonably* be thought to advance" the purpose of "encouraging pharmacies to locate in all parts of Puerto Rico." 405 F.3d at 60 (emphasis added). The Commonwealth begs to differ. First of all, the Court of Appeals should not have lightly discarded the reasoning employed by Congress when it approved the 1974 Act, which required just this sort of certificate requirements. Moreover, the Court of Appeals' reasoning is simply wrong. That a health care provider has been denied a CON for a particular location does not automatically mean that it will simply give up in its attempt to open a facility; to the contrary, the idea behind the program is to force providers to at least consider establishing themselves in locations in which there is a greater need for their services. Even if those locations were not at the top of their list, because the providers might not be able to obtain as large a profit as they would in their preferred location, this does not mean that the underserved location would be *un*profitable.

Applicable law: The dormant Commerce Clause

The Constitution grants Congress the power to regulate commerce among the several States. U.S. Const. Art. I, § 8, cl. 3. This Clause has been interpreted to contain a negative aspect, known as the dormant Commerce Clause, which limits the power of the states to "discriminate" against interstate commerce. This Court has long held that, "in all but the narrowest circumstances, state laws violate the Commerce Clause if they mandate 'differential treatment of in-state and out-of-state economic interests that benefits the former and burdens the latter.'" *Granholm v. Heald*, 125 S. Ct. 1885, 1895 (2005) (citing *Oregon Waste Systems, Inc. v. Department of Environmental Quality of Ore.*, 511 U.S. 93, 99 (1994)).

Because Congress's power over commerce is plenary, *see, e.g., Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1, 196-97 (1824), the dormant Commerce Clause doctrine merely establishes a default rule of neutrality toward interstate commerce that is applicable only where Congress has not spoken. "When Congress so chooses, state actions which it plainly authorizes are invulnerable to constitutional attack under the Commerce Clause." *Northeast Bancorp v. Board of Governors*, 472 U.S. 159, 174 (1985). "If Congress ordains that the States may freely regulate an aspect of interstate commerce, any action taken by a State within the scope of the congressional authorization is rendered invulnerable to Commerce Clause challenge." *W. & S. Life Ins. Co. v. State Bd. of Equalization*, 451 U.S. 648, 652-53 (1981); *see also Hillside Dairy Inc. v. Lyons*, 539 U.S. 59, 66 (2003); *Prudential Ins. Co. v. Benjamin*, 328 U.S. 408, 412 (1946). Congress may "confer . . . upon the States an ability to restrict the flow of interstate commerce that they

would not otherwise enjoy." *Lewis v. BT Inv. Managers, Inc.*, 447 U.S. 27, 44 (1980); *see also, e.g.*, *New York v. United States*, 505 U.S. 144, 171 (1992); *Wyoming v. Oklahoma*, 502 U.S. 437, 458 (1992).[8]

Only where Congress has not authorized, either expressly or by clear implication, state legislation that might discriminate against or unduly affect interstate commerce does it become necessary to subject such state statutes to dormant Commerce Clause scrutiny. Even then, however, it is clear that while the purpose of the dormant Commerce Clause is to protect interstate markets from discriminatory regulation, it does *not* protect particular interstate firms, from prohibitive or burdensome regulations. *Exxon Corp.*, 437 U.S. at 127-28.

A constitutional challenge of a statute under the dormant Commerce Clause requires a two-tiered examination of the statute: first, whether the statute's purpose and practical effect is to discriminate against interstate commerce; and, second, whether the statute regulates even-handedly with only 'incidental' effects on interstate commerce. *Oregon Waste Systems*, 511 U.S. at 99. If the court finds that the statute discriminates against interstate commerce, the statute is, generally, struck down without further inquiry. Nevertheless, if the court finds that the statute is not discriminatory but, instead, that it

---

[8] This rule is not without detractors. *See, e.g.*, Norman R. Williams, *Why Congress May Not "Overrule" the Dormant Commerce Clause*, 53 UCLA L. Rev. 153, 238 (2005) ("the Constitution's commitment to economic union and democratic accountability precludes Congress from validating state laws that would otherwise violate the Dormant Commerce Clause"). For the moment, however, it remains firmly entrenched in the case law.

has only "incidental" effects on interstate commerce, then, the court must determine whether the statute imposes a burden on interstate commerce that is "*clearly* excessive in relation to the putative local benefits." *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970) (emphasis added). *See also C & A Carbone*, 511 U.S. at 390; *Oregon Waste Systems*, 511 U.S. at 99; *Brown-Forman Distillers Corp. v. New York State Liquor Authority*, 476 U.S. 573, 579 (1986); *Chemical Waste Management, Inc. v. Hunt*, 504 U.S. 334, 342 (1992).[9]

As already mentioned, the CNC Act was authorized by Congress, which makes it unnecessary to engage in any sort of dormant Commerce Clause analysis. Moreover, even if the CNC Act were properly subject to dormant Commerce Clause scrutiny, it is clearly facially-neutral with respect to interstate commerce, as the Court of Appeals recognized. It was also not intended to protect the interests of local competitors; any such protection is *merely incidental* to the goals of cost-containment and

---

[9] The Commonwealth is aware that at least two Justices of this Court appear to disagree with the *Pike* balancing test, and, indeed, with the theoretical underpinnings of the dormant Commerce Clause doctrine as a whole. *See, e.g., Camps Newfound/Owatonna, Inc. v. Town of Harrison*, 520 U.S. 564, 612-14 (1997) (Thomas, J., dissenting); *Tyler Pipe Indus., Inc. v. Wash. State Dep't of Revenue*, 483 U.S. 232, 260-62 (1987) (Scalia, J., concurring in part and dissenting in part). Whether these criticisms are valid has been the subject of recent scholarship. *See, e.g.*, Brannon P. Denning, *Justice Thomas, the Import-Export Clause, and Camps Newfound/Owatonna v. Harrison*, 70 U. Colo. L. Rev. 155 (1999) (defending current dormant Commerce Clause understandings against Justice Thomas's criticisms); Brannon P. Denning, *Why the Privileges and Immunities Clause of Article IV Cannot Replace the Dormant Commerce Clause Doctrine*, 88 Minn. L. Rev. 384 (2003) (same). In any case, however, because *Pike* has not been overruled, the discussion above assumes its continuing validity.

efficiency in health care planning, and the strong state interest in protecting the health of its citizens, which Congress shared at the time that the 1974 Act was adopted. Thus, at worst, the Court of Appeals should have analyzed the constitutionality of the CNC Act under the *Pike* balancing test, instead of analyzing and invalidating it under the strict scrutiny standard designed for discriminatory regulations. By not doing so, the First Circuit unnecessarily cast into doubt the continuing validity of 37 States' CON programs.

Even though it was repealed in 1986, the 1974 Act continues to shield the CNC Act, as well as other state CON laws, from dormant Commerce Clause scrutiny.

The 1974 Act provided the States with a *quid pro quo*: enact legislation creating CON programs, and certain federal funds will be made available. Forty-nine States and the Commonwealth of Puerto Rico accepted this offer. Twelve years later, during the second Reagan administration, Congress repealed the 1974 Act, thus no longer requiring States to establish CON programs in order to receive the federal health funds in question. *See* Section 701 of the Drug Export Amendment Act of 1986, Pub. L. No. 99-660, 100 Stat. 3743, 3799 ("Title XV of the Public Health Service Act '42 USC 300k-1 *et seq.*' is repealed effective January 1, 1987").

Tellingly, Congress did nothing more. It did not, for example, declare the State CON programs to be invalid, or even discourage States from continuing to enforce them. In the end, one can hypothesize various reasons why Congress may have repealed the 1974 Act, such as, perhaps, a shift in preferences from government planning to market-based solutions, but neither the statute nor the available

legislative history confirms any given hypothesis. The statute was simply repealed.

Were the 1974 Act still in force, there would be no question that Puerto Rico's CNC Act would be impervious to dormant Commerce Clause challenges, because it would be expressly authorized by Congress. The question is, then, whether the 1986 repeal of the 1974 Act should change this result; and the answer, the Commonwealth respectfully submits, is no.

Although none of the opinions of this Court that the Commonwealth has been able to find has addressed this precise question, the general nature of the inquiry seems clear enough: did Congress clearly intend to permit States to enact certain types of economic legislation, even if that legislation was otherwise either clearly invalid or of doubtful validity under the dormant Commerce Clause doctrine? Based on this general framework, an answer to the question presented can be devised.

First, one is not dealing with a *tabula rasa*. To the contrary, by means of the 1974 Act, Congress affirmatively encouraged States to adopt CON legislation. This must then serve as the baseline for determining Congress's *current* views on the validity of State CON programs, which, after all, were adopted in reasonable reliance of Congress's approval. Viewed from that perspective, it seems evident that, when Congress repealed the 1974 Act, yet said nothing about the State CON programs, it was not reversing its earlier authorization of these programs. Congress certainly had the opportunity to speak directly to the issue, had it wished to do so. Having once expressed a clear intent on this matter, it should not be deemed to have changed that intent except through an equally clear

expression of intent. This did not occur in 1986, nor has it at any time since.

Even if CON programs, such as the CNC Act, were subject to dormant Commerce Clause scrutiny, they would pass muster because they do not discriminate against interstate commerce; at worst, the statute has only "incidental" effects on interstate commerce that are *not* clearly excessive in relation to its putative local benefits.

As the Court of Appeals recognized, the CNC Act serves the legitimate public goal of seeking to protect the health of the public in Puerto Rico. This, of course, is the same policy view reflected in Congress's findings, contained in Section 2 of the 1974 Act. It is also in keeping with the traditional view that "a state has broad power to establish and enforce standards of conduct within its borders relative to the health of everyone there. It is a vital part of a state's police power. The state's discretion in that field extends naturally to the regulation of all professions concerned with health." *Barksy v. Bd. of Regents*, 347 U.S. 442, 449 (1954).

The CNC Act serves as a guideline for the orderly and efficient growth of health facilities and services. Because the states have a legitimate concern in the health of their citizens, and the establishment of health services is directly related to the health, safety and welfare of their surrounding communities, the states may adopt regulations that compliment the federal efforts already in force. The provision of pharmaceutical services, for example, is subject to the federal regulations imposed by the Food and Drug Administration and the Drug Enforcement Administration, and also to state regulation of licensing and

quality control. *See generally* Nicholas P. Terry, *Prescriptions sans frontières (or How I Stopped Worrying about Viagra on the Web but Grew Concerned about the Future of Health Care Delivery)*, 4 Yale J. Health Pol'y, L. & Ethics 183 (2004). The exercise of the police power in this area is particularly important given the role of pharmacists as "health care providers who accept responsibility for the outcomes of drug therapy by accurately processing medication orders, detecting and rectifying potential problems with drug therapy, counseling patients concerning the anticipated effects of drugs, and monitoring the results of drug use." William L. Allen, David B. Brushwood, *Pharmaceutically Assisted Death and the Pharmacist's Right of Conscience*, 5 J. Pharmacy & L. 1 (1996).

In sum, because the statute is not facially discriminatory, and was adopted for purposes of protecting the health of citizens of Puerto Rico and of coordinating health services in accordance with the incentives offered by the 1974 Act, it should be evaluated, if at all, under the *Pike* balancing test.

1. The grandfather clause of the CNC Act serves a legitimate purpose and was necessary for avoiding unfair results to already-established pharmacies and other health facilities.

The Court of Appeals improperly inferred that the CNC Act discriminates against out-of-Commonwealth pharmacies because it has a grandfather clause, which provides in pertinent part that "any person who is operating a pharmacy established before October 24, 1979 . . . shall be entitled to have the Secretary issue a certificate of necessity and convenience without the requirement

of the determination of public necessity and convenience and without the holding of a hearing." 24 P.R. Laws Ann. § 334g.

This Court has consistently validated the inclusion of grandfather clauses within the regulatory schemes for the issuance of certificates of necessity and convenience. *See Crescent Express Lines v. United States,* 49 F. Supp. 92, 94 (D.C.N.Y. 1943) (grandfather clause "was apparently inserted to avoid the hardship which would result from forcing a carrier to justify his existing business in terms of public convenience"), *aff'd,* 320 U.S. 401 (1943); *United States v. Carolina Freight Carriers Corp.,* 315 U.S. 475, 481 (1949) ("the purpose of the 'grandfather clause' was to assure those to whom Congress had extended its benefits a substantial parity between future operations and prior bona fide operations").

The purpose of a grandfather clause is to exempt from statutory regulations imposed for the first time on a trade or profession those members who are already engaged in the newly regulated field in order to avoid unfair results. Consonant with this notion of fairness, most, if not all CON programs nationwide have an exemption for those health facilities or services that were in force at the time of the enactment of the CON legislation. For example, the State of North Carolina exempts from its CON program those "projects which received the requisite federal approval prior to January 1, 1979, and on which construction was commenced before January 1, 1980." *Rutherford Hospital v. RNH Partnership,* 168 F.3d 693, 698 (4th Cir. 1999) (citing *In re Wilkesboro, Ltd.,* 285 S.E. 2d 626 (1982)).

The grandfather clause of the CNC Act does not impermissibly burden interstate commerce. To the contrary, the clause makes a reasonable and neutral distinction between the pharmacies established prior to 1979, *including twelve (12) pharmacies owned by Walgreen*, and the pharmacies established at a later date. Clearly, this differential treatment is unrelated to interstate commerce. The fact that the majority of the pharmacies exempted by the grandfather clause were owned by local entities at the time of the exemption is not indicative of discrimination.[10]

2. The one-mile-radius limit on standing to oppose the issuance of a certificate of need and convenience effectively bars discrimination against interstate commerce.

The decision by the Court of Appeals affords excessive weight to the fact that pharmacies located within a one-mile radius of the proposed location may oppose the grant of a CNC and trigger the administrative hearing process. According to the Court, "the Secretary invokes this authority [to deny a CNC] only upon the urging of a member of the largely local group of existing pharmacies, thereby permitting a predominantly local group to manipulate the regulatory scheme for its own advantage." *Walgreen*, 405 F.3d at 57.

---

[10] The Court of Appeals improperly relied on *Pac. Northwest Venison Producers v. Smitch*, 20 F.3d 1008 (9th Cir. 1994), in support of the proposition that grandfather clauses can be indicative of discrimination. *See Walgreen*, 405 F.3d 55-56. Contrary to the First Circuit's reading, however, the Ninth Circuit's opinion held that such "exceptions are perhaps the only reasonable means" of attaining the particular goal of a regulation. 20 F.3d at 1013.

This reasoning is flawed for various reasons. First, the one-mile requirement is precisely what keeps already established pharmacies from manipulating the regulatory scheme. Only those pharmacies that are established within a one-mile radius of the proposed location can file an opposition, and the number of possible oppositions is narrowed down even further by the fact that the Regulation requires them to be filed within fifteen (15) days from the publication of the CNC petition.

Additionally, the one-mile provision is a narrowly-drawn measure that serves a legitimate local purpose[11] and outweighs any burdens that the CNC Act might have on interstate commerce. It is not only a useful tool of enforcement for the CNC Act, but also a reasonable and neutral measure that operates independently of any in- or out-of-Commonwealth distinctions. It is undisputed that Walgreen, as well as any other out-of-Commonwealth pharmacy, may oppose the establishment of a local pharmacy as long as it is located within the one-mile radius of the proposed location.[12]

---

[11] This Court has recognized, within the context of the due process clause, that the "[s]tates may, through general ordinances, restrict . . . the geographical location of commercial enterprises." *New Motor Vehicle Board of California v. Orrin W. Fox Co.*, 439 U.S. 96, 107 (1978) (citing *Williamson v. Lee Optical*, 348 U.S. 483, 491 (1955)).

[12] In fact, Walgreen has intervened in several CNC petitions filed by other pharmacies.

3. The evidence on record is insufficient to support an inference of discrimination against interstate commerce.

Petitioner disputes the reversal by the Court of Appeals of the District Court's factual findings and weighing of the evidence on record. As this Court has explained, any statistical evidence needs to be interpreted with caution and in light of the surrounding circumstances. *See International Bd. of Teamsters v. United States,* 431 U.S. 324, 340 (1977) ("statistics are not irrefutable; they come in infinite variety and, like any other kind of evidence, they may be rebutted. In short, their usefulness depends on all of the surrounding facts and circumstances.").

In the case at bar, using the number of establishments as the variable to measure the relative importance of local pharmacies presents only a partial and subjective view of the market. The numbers would be significantly different if the value of sales had been used as the variable instead, since the average amount of sales in chain pharmacies such as Walgreen tends to be substantially larger than those in smaller, local pharmacies.

Additionally, it is entirely plausible that most of the local petitions are likely to be unopposed because they are directed towards "unattended areas" (i.e., outside the one-mile radius of an existing pharmacy), whereas most out-of-Commonwealth petitions are prone to opposition because they are directed towards already "saturated areas." One only needs to drive through a few cities in Puerto Rico in order to ascertain that out-of-Commonwealth pharmacies such as Walgreen, K-Mart and Wal-Mart have almost always been established in areas that already had a high concentration of business establishments, including other

pharmacies. It should be noted that all unopposed petitions filed by Walgreen and other out-of-Commonwealth petitioners were automatically granted. Perhaps most importantly, of the 58 CNC petitions submitted by Walgreen from 1979 to 2001, 43 were initially granted, and the 15 that were originally rejected were eventually granted, as well.

Furthermore, the record unequivocally shows that the out-of-Commonwealth petitioners that have been granted a certificate of necessity actually operate very profitable businesses in Puerto Rico. In fact, there are more Walgreen pharmacies in Puerto Rico than in more than half of the forty-five (45) states in which it is operates. There are currently about sixty-three (63) Walgreen pharmacies operating in Puerto Rico, a number that is surpassed in only seventeen (17) other states, all of which have larger populations than Puerto Rico.

In sum, the numbers used by the Court of Appeals are more consistent with the hypothesis that the likelihood that a particular CNC petition will be denied is directly correlated, not with the fact that an applicant may be an out-of-Commonwealth corporation, but with the number of existing pharmacies within the one-mile radius of the proposed location, which are the only ones entitled to oppose the petition. *See Walgreen*, 292 F. Supp. 2d at 315, App. 45 ("[t]he numerical differential relates to opposed petitions"). Thus, the evidence on the record is ambiguous at best and, as such, it should have been interpreted in Petitioner's favor.

The fact that the Court of Appeals misread the record bespeaks a willingness to reject the proffered justifications for CON programs, which, if its opinion is not reversed, could be used in future cases to undermine the remainder of Puerto Rico's CNC Act, as well as other States' CON programs.

CONCLUSION

For the foregoing reasons, the instant petition for certiorari should be granted, and the judgment below reversed.

Respectfully submitted,

MIGUEL A. SANTANA-BAGUR
Deputy Attorney General of Puerto Rico
Counsel of Record

SALVADOR J. ANTONETTI-STUTTS
Solicitor General of Puerto Rico

MARIANA D. NEGRÓN-VARGAS
Deputy Solicitor General

MAITE ORONOZ-RODRÍGUEZ
Deputy Solicitor General

DORALIZ E. ORTIZ-DE-LEÓN
Assistant Solicitor General
Department of Justice
P.O. Box 9020192
San Juan, Puerto Rico 00902-0192
Tel. (787) 724-2165 Ext. 2707
Fax (787) 724-3380

TABLE OF CONTENTS

United States Court of Appeals
For the First Circuit

No. 03-2542

WALGREEN CO., WALGREEN OF SAN PATRICIO, AND WALGREEN OF PUERTO RICO,

Plaintiffs, Appellants,

v.

JOHN V. RULLAN, SECRETARY OF THE PUERTO RICO HEALTH DEPARTMENT,

Defendant, Appellee.

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF PUERTO RICO

[Hon. Héctor M. Laffitte, *U.S. District Judge*]

Before

Boudin, *Chief Judge*,

Lipez and Howard, *Circuit Judges*.

Henry C. Dinger, P.C., with whom Stephen D. Poss, P.C. and Goodwin Procter, LLP were on brief, for appellants.

Camelia Fernández-Romeu, with whom Roberto J. Sánchez-Ramos, Puerto Rico Department of Justice, Office of the Solicitor General, was on brief, for appellee.

April 22, 2005

HOWARD, Circuit Judge. Walgreen Co., Walgreen of San Patricio, and Walgreen of Puerto Rico (collectively, Walgreen) sued John V. Rullan, the Secretary of the Puerto Rico Health Department (Secretary), under 42 U.S.C. § 1983, challenging the constitutionality of a Commonwealth of Puerto Rico statute requiring that all pharmacies seeking to open or relocate within the Commonwealth obtain a "certificate of necessity and convenience." 24 L.P.R.A. § 334 *et. seq.* Walgreen asserts that this statute is unconstitutional because it impermissibly discriminates against or excessively burdens interstate commerce and violates due process. The district court rejected these arguments. Because we conclude that the statute impermissibly discriminates against interstate commerce, we reverse.

I. Background

In 1974, Congress passed the National Health Planning and Resources Development Act. *See* Pub. L. No. 93-641, 88 Stat. 2225 (1975). This statute was designed to correct perceived imperfections in the health care market. Among its goals, the statute was intended to restrict skyrocketing health care costs and prevent the unnecessary duplication of services. *See* Patrick John McGinley, *Beyond Health Care Reform: Reconsidering Certificate of Need Laws in a Managed Competition System*, 23 Fla. St. U. L. Rev. 141, 154-55 (1995).

To achieve these goals, Congress, *inter alia*, conditioned the states' receipt of certain federal funds on the enactment of "certificate of need programs." Under these programs, the states reviewed proposed health care facility construction projects and permitted projects to proceed only after a demonstration of sufficient need for the services.[1] *See generally* Lauretta H. Wolfson, *State Regulation of Health Facility Planning: The Economic Theory and Political Realities of Certificates of Need*, 4 DePaul J. Health Care L. 261 (2001).

In 1975, Puerto Rico (which is treated as a state for present purposes) responded to the federal initiative by enacting a "certificate of need" law. 24 L.P.R.A. §§ 334 *et seq.* (the Act). The Act provided that no person may "acquire or construct a health facility . . . without having first obtained a certificate of necessity and convenience granted by the Secretary." *Id.* § 334a. The Act defined a certificate of necessity and convenience as a

> document issued by the Secretary of Health authorizing a person to carry out any of the activities covered by [the Act], certifying that the same is necessary for the population it is to serve and that it will not unduly affect the existing services, thus contributing to the orderly and adequate development of health services in Puerto Rico.

---

[1] One of the purposes of encouraging states to enact certificate of need programs was to limit the excessive construction of health care facilities by physician-owned investments. Because physicians could prescribe the use of these newly-constructed facilities, Congress postulated that doctors were ordering unnecessary, expensive procedures to create artificial demand for their investments. *See* McGinley, *supra* at 154-55.

Id. at § 334(e). The Act identified "health facilities" required to obtain a certificate, *id.* § 334(d), provided criteria for granting a certificate, *id.* § 334b, permitted the Secretary to promulgate additional certificate criteria, *id.* § 334j, and established administrative and judicial review procedures governing the certificate review process, *id.* §§ 334f-2 to 334f-14.

As originally enacted in 1975, the Act did not apply to pharmacies. Four years later, the Puerto Rico legislature amended the definition of "health care facilities" to include pharmacies. *See* Law No. 189 of July 29, 1979, amending 24 L.P.R.A. §§ 334 *et seq.* This amendment, *inter alia*, provided that any pharmacy in existence on October 24, 1979 was exempt from the certificate requirement. *See* 24 L.P.R.A. § 334g. When the amendment was enacted, over ninety-two percent of pharmacies operating in Puerto Rico were locally-owned concerns. There is no legislative history surrounding the enactment of the amendment, but the Secretary asserts that the purpose of the amendment was to encourage the location of pharmacies in underserved areas of Puerto Rico. Puerto Rico is the only jurisdiction that has applied its certificate of need law to pharmacies.

Twelve years after its enactment, Congress repealed the National Health Planning and Resources Development Act. Pub. L. No. 99-60, 100 Stat. 3743 (1986). While several states followed suit by repealing their certificate of need laws, Puerto Rico's remains in effect.

As mentioned above, the Act provides detailed procedures for the certificate approval process. The process begins with a proposed pharmacy submitting a letter advising the Health Department of its intention to file a

certificate request. Within thirty days of sending this letter, the proposed pharmacy must file the formal certificate application. *See* 24 L.P.R.A. § 334f-3.

After the Secretary receives the application, he publishes a notice in a widely read newspaper announcing the request. *See id.* § 334f-6. He also notifies all "affected persons" by mail. *See* Regulation of the Secretary of Health No. 56, art. IV § 2(b) (1980) ("Regulation No. 56"). Among the "affected persons" are existing pharmacies located within one mile of the proposed pharmacy site. These entities then have the right to oppose the granting of a certificate to the proposed pharmacy provided that they give written notice of their opposition to the Secretary and proposed pharmacy within 15 days. *Id.*

Once the notification process is complete, the Secretary almost always issues the certificate if no one objects. *See infra* at n.3. But if there is opposition from an "affected person," which the Secretary acknowledges is, without exception, an existing pharmacy located within one mile of the proposed pharmacy site, the Secretary assigns the case to the Health Department's Hearings Division for an administrative hearing. The hearing is often delayed to permit the parties time for discovery. At the hearing, the parties present, *inter alia,* expert testimony concerning the expected impact that the proposed pharmacy will have on competition in the local area. At the conclusion of the hearing, the parties submit proposed findings of fact and conclusions of law. The hearing officer then forwards a recommendation to the Secretary for final action.

In making his final determination, the Secretary considers various statutory criteria, including:

> (1) the relationship between the transaction for which the certificate is requested, and the long-term service development plan, if any, of the petitioner;
>
> (2) the present and projected need of the population which will be affected by the proposed transaction of the services to be provided thereby;
>
> (3) the existence of alternatives to the transaction for which the certificate is requested, or the possibility of providing the proposed services in a more efficient or less costly manner than that proposed by the petitioner; and
>
> (4) the relationship between the health system operating in the area and the proposed transaction.

24 L.P.R.A. § 334b. In addition, the Secretary considers other criteria, established by regulation, including whether the proposed pharmacy will benefit certain "unattended populations" (e.g., low-income, disabled, or elderly populations) and whether the proposed pharmacy will be located in an area that is already "saturated" by existing pharmacies. Regulation No. 56, art. V. § 1(f) & art. VI § 13(2).

After the Secretary rules on the certificate request, the losing party may ask for reconsideration. *See* 24 L.P.R.A. § 334f-10. The losing party may also seek judicial review in the Puerto Rico Circuit Court of Appeals and eventually in the Puerto Rico Supreme Court. *See id.* Typically, the judicial review process takes in excess of a year to conclude, and the Secretary's decision is often stayed during this period. Thus, even if the certificate is

ultimately granted, the entire administrative and judicial process usually takes several years to complete.

II. The District Court Opinion

In the district court, Walgreen claimed that the Act, as applied to retail pharmacies, is invalid because it discriminates against or excessively burdens interstate commerce. After filing cross motions for summary judgment, the parties agreed to try the case on affidavits, depositions, and exhibits.[2] In a published opinion, the district court rejected Walgreen's claims. *See Walgreen Co. v. Rullan*, 292 F.Supp. 2d 298 (D.P.R. 2003).

The district court rejected Walgreen's discrimination argument because the Act requires "any local economic interest seeking to obtain a [certificate to] jump through the same bureaucratic hoops" as an out-of-Commonwealth entity and thus treats all "newcomers" evenhandedly. *Id.* at 313. The court also declined to find discrimination, even though all existing pharmacies were exempt when the Act was amended to include pharmacies, because "the statute made no distinction between local and national pharmacies." *Id.* at 315. After concluding that the Act was non-discriminatory, the court determined that the Act did not excessively burden commerce. *See id.* at 316-17. The court ruled that the Act imposes minimal burdens on

[2] The parties state that, by asking the court to decide the case on the paper record, they "waived" trial. This is an inaccurate description of the procedure. By submitting the paper record and asking the court to make findings of fact and conclusions of law based on these materials, the parties consented to a trial on a stipulated record. *See, e.g., AIDS Action Comm. v. MBTA*, 42 F.3d 1, 5 (1st Cir. 1994).

interstate commerce because it does not prohibit out-of-Commonwealth pharmacies from entering the Puerto Rico market. *See id.* The court also recognized the Act's legitimate purpose of encouraging pharmacies to locate in underserved areas of Puerto Rico, though recognizing that Walgreen presented a "solid case" that the Act was not helping the Commonwealth achieve this goal. *Id.* at 310, 317-18. Thus, the court held that "[g]iven the Act's modest burden on *interstate* commerce," the "burden is clearly [not] excessive in relation to its *putative* local benefits." *Id.* at 318 (emphasis in original).

III. Discussion

On appeal, Walgreen renews its arguments challenging the constitutionality of the Act as applied to retail pharmacies. Because Walgreen appeals the district court's decision following a bench trial, we review factual findings for clear error and conclusions of law *de novo*. *See Keyes v. Sec'y of the Navy*, 853 F.2d 1016, 1020 (1st Cir. 1988).

The Constitution grants Congress the power to regulate interstate commerce. *See* U.S. Const. art. I, § 8, cl. 3. While the Commerce Clause's text provides only an affirmative grant of power, for over 150 years, the Clause has been interpreted to contain a negative aspect known as the dormant Commerce Clause. *See* Laurence H. Tribe, 1 *American Constitutional Law* 1030 (3d ed. 2000) (citing *Cooley v. Bd. of Wardens*, 53 U.S. 299, 317-20 (1852)). The dormant Commerce Clause doctrine, which applies to Puerto Rico on the same terms as it applies to the states, *see United Egg Producers v. Dep't of Agric. of P.R.*, 77 F.3d 567, 569 (1st Cir. 1996), limits the power of states "to erect barriers against interstate trade," *Lewis v. BT*

Investment Managers, Inc., 447 U.S. 27, 35 (1980); *see also Doran v. Mass. Turnpike Auth.*, 348 F.3d 315, 318 (1st Cir. 2003).

Under the dormant Commerce Clause, if a state law has either the purpose or effect of significantly favoring in-state commercial interests over out-of-state interests, the law will "routinely" be invalidated "unless the discrimination is demonstrably justified by a valid factor unrelated to economic protectionism." *Houlton Citizens' Coalition v. Town of Houlton*, 175 F.3d 178, 184 (1st Cir. 1999) (quoting *West Lynn Creamery, Inc. v. Healy*, 512 U.S. 189, 192-93 (1994)). If the state law regulates in-state and out-of-state interests evenhandedly, the statute will be upheld "unless the burden imposed on [interstate] commerce is clearly excessive in relation to the putative local benefits." *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970).

While these rules are easy to recite, their application to a particular factual setting is often difficult. Recognizing this difficulty, the Supreme Court has cautioned that the dormant Commerce Clause inquiry should be undertaken by "eschew[ing] formalism for a sensitive, case-by-case analysis of purposes and effects." *West Lynn Creamery*, 512 U.S. at 201. With these principles in mind, we consider whether Puerto Rico's certificate of need law, as applied to retail pharmacies, discriminates against interstate commerce.

On its face, the Act applies neutrally. All commercial interests wishing to open or relocate a pharmacy in Puerto Rico must obtain the same certificate no matter their place of origin. But viewed more critically and in light of the

Secretary's enforcement of the Act, the Act discriminates against interstate commerce by permitting the Secretary to block a new pharmacy from locating in its desired location simply because of the adverse competitive effects that the new pharmacy will have on existing pharmacies.

As set forth above, when the Puerto Rico legislature amended the Act in 1979 to include pharmacies as covered "health care facilities," it exempted all existing pharmacies from the certificate requirement. 24 L.P.R.A. § 334g. Of the pharmacies operating in Puerto Rico at this time, ninety-two percent were locally owned. Thus, the Act, as amended, excused an almost entirely local class of pharmacies from the certificate requirement. *Cf. Pac. Northwest Venison Producers v. Smitch*, 20 F.3d 1008, 1013 (9th Cir. 1994) (recognizing that "grandfather clause" exempting in-state interests can indicate discriminatory nature of statute) (citing *Raymond Motor Transp., Inc. v. Rice*, 434 U.S. 429, 447 (1978)).

What's more (again as set forth above) this group of existing pharmacies not only was excused from the certificate requirement but also has been permitted to wield substantial influence in the enforcement of the certificate requirement against proposed new pharmacies. The Secretary acknowledges that, unless an existing pharmacy objects to a certificate request, he almost invariably issues the certificate. Yet when there is an objection, he begins the costly and time-consuming administrative and judicial procedures established by the Act and frequently declines to issue requested certificates at the conclusion of the process.

Thus, in practice, the Act permits an existing pharmacy to object simply because it fears additional competition.

And this practice is not only within the letter of the Act, it is within its spirit as well. The Act provides that the Secretary may deny a certificate if a new pharmacy will "unduly affect existing services." 24 L.P.R.A. § 334(e). Moreover, the regulations enforcing the Act direct the Secretary to reject a new pharmacy's request if the proposed location is already "saturated" with existing pharmacies. Regulation No. 56, art. VI § 13(2). The law is thus protectionist both *de jure* and *de facto*.

This protectionist regime has had discriminatory effects. While the Secretary has rejected virtually no unopposed applications,[3] twenty-three percent of opposed applications have been denied. The negative effects on out-of-Commonwealth applicants have been particularly pronounced. Over fifty percent of out-of-Commonwealth entities have been forced to undergo the entire administrative process compared to less than twenty-five percent of local applicants. Moreover, of those applicants forced to endure the hearing process, the Secretary has granted certificates to ninety percent of the local applicants but only to fifty-eight percent of out-of-Commonwealth applicants. In 1979, ninety-two percent of pharmacies were under local ownership, and in 2001, ninety-four percent of pharmacies were locally owned. The statistical evidence thus strongly indicates that the Act, as applied by the Secretary, has limited competition in favor of the predominantly local group of existing pharmacies.

The Supreme Court has invalidated, on dormant Commerce Clause grounds, regulatory schemes that

---

[3] Out of the 337 unopposed applications, only one has been rejected.

permit a state to deny an operating license on the basis that the opening of a new facility in a particular location will cause undue competition for existing facilities.[4] *See H.P. Hood & Sons, Inc. v. DuMond*, 336 U.S. 525, 545 (1948) (invalidating state agency's refusal to grant a license for a milk producer to operate in a desired locality because the relevant market was "already adequately served"); *Buck v. Kuykendall*, 267 U.S. 307, 314-16 (1925) (invalidating a rule that a state could deny an interstate transporter a certificate of necessity and convenience to use state roads because the "area is already being adequately served"); *George W. Bush & Sons Co. v. Maloy*, 267 U.S. 317, 318 (1925) (similar); *see also Medigen of Ky. v. Pub. Serv. Comm'n of W. Va.*, 787 F. Supp. 590, 598 (S.D. W. Va. 1991) (collecting cases invalidating various certificate of convenience and necessity schemes because they discriminate against interstate commerce), *aff'd* 985 F.2d 164 (4th Cir. 1993). A court has also struck down, on dormant Commerce Clause grounds, a law which gave in-state interests the ability to manipulate a facially neutral regulatory scheme to establish advantages over out-of-state interests. *See McNeilus Truck & Mfg. v. Ohio*, 226 F.3d 429, 442-43 (6th Cir. 2000) (holding that facially

---

[4] This is not to say that there are no instances in which a state could justify a certificate of need law that restricts competition, *see, e.g., Panhandle E. Pipe Line Co. v. Mich. Pub. Serv. Comm'n*, 341 U.S. 329, 333-34 (1951); *Am. Motors Sales Corp. v. Div. of Motor Vehicles*, 592 F.2d 219, 222-23 (4th Cir. 1979); however, certificate of need laws which deter competition simply to benefit those entities already operating within a state are not legitimate exercises of state power, *see Philadelphia v. New Jersey*, 437 U.S. 617, 624 (1978) (stating that laws which have a disproportionately negative impact on out-of-state businesses and serve only to promote "economic protectionism" are "*per se*" invalid).

neutral scheme which gave established local interests the ability to block licensing of out-of-state entities by refusing to contract with them had the effect of discriminating against interstate commerce).

The Act, insofar as it applies to pharmacies, suffers from both of these infirmities. It permits the Secretary to deny a proposed pharmacy market access at its desired location simply to limit competition. Further, the Secretary invokes this authority only upon the urging of a member of the largely local group of existing pharmacies, thereby permitting a predominantly local group to manipulate the regulatory scheme for its own advantage. For these reasons, the Act discriminates against commerce by permitting established pharmacies "to retard, burden or constrict the flow of . . . commerce for their own economic advantage." *See H P Hood & Sons*, 336 U.S. at 665.

The Secretary advances several arguments defending the Act. First, he claims that the Act does not burden commerce sufficiently to trigger the dormant Commerce Clause doctrine because it does not bar any out-of-Commonwealth pharmacy from operating in Puerto Rico. He contends that the Act is permissible because every pharmacy can open *somewhere* on the island.

This argument takes too narrow a view of the kind of restrictions that affect the flow of commerce. Laws may implicate the Commerce Clause if they ban a business from establishing operations in only one part of a state, even though the rest of the state remains open. *See Dean Milk Co. v. Madison*, 340 U.S. 349, 354-56 (1951) (holding invalid an ordinance which bars certain milk producers from selling milk within city limits); *accord Fort Gratiot Sanitary Landfill, Inc. v. Mich. Dep't of Natural Resources*,

504 U.S. 353, 361 (1993) ("[O]ur prior cases teach that a State may not avoid the strictures of the Commerce Clause by curtailing the movement of articles of commerce through subdivisions of the State, rather than through the State itself."). By permitting the Secretary to bar the opening of a new pharmacy in its desired location because of the competitive effects on existing pharmacies, the Act limits the parts of Puerto Rico which are open to new retail pharmacies. This burden on commerce is sufficient to trigger the Commerce Clause scrutiny.[6]

Contrary to the Secretary's suggestion, the Act also cannot be defended on the ground that it treats all newcomers equally and thus does not discriminate because every pharmacy seeking to open or relocate within Puerto Rico must obtain a certificate. While it is true, as the Secretary states, that a statute is consonant with the dormant Commerce Clause so long as it "leaves all comers with equal access to the local market," *see Houlton Citizens' Coalition*, 175 F.3d at 188, this principle has no application here.

In *Houlton Citizens' Coalition*, the plaintiff challenged the city's award of a contract providing the exclusive right to process the city's municipal waste. *Id.* at 181-82. We

---

[6] That the Act regulates the ownership of local businesses rather than the flow of goods into the Commonwealth does not affect this conclusion. *See Lewis*, 447 U.S. at 38-39; *see also Yamaha v. Jim's Motorcycle, Inc.*, 401 F.3d 560 (4th Cir. Mar. 28, 2005) (invalidating, on dormant Commerce Clause grounds, state law which regulated the ownership of local motorcycle franchises to prevent excessive competition with existing franchises).

rejected a dormant Commerce Clause challenge to the awarding of the contract because "in-state and out-of-state bidders [were] allowed to compete freely on a level playing field" as the bidding process did not favor any particular interest. *Id.* at 188. But unlike the bidding process at issue *Houlton Citizens' Coalition*, the Act provides different "playing fields" for in and out-of-state interests. While the Act treats "newcomers" equally, it gives an on-going competitive advantage to the predominantly local group of existing pharmacies. 24 L.P.R.A. § 334g. In this crucial respect, the Act is dissimilar to the regulatory conduct challenged in *Houlton Citizens' Coalition*, and is akin to laws which courts have invalidated because they discriminate against out-of-state entities and *some* in-state entities in order to favor a subset of in-state interests. *See C & A Carbone, Inc. v. Clarkstown*, 511 U.S. 383, 391 (1994) ("The ordinance is no less discriminatory because in-state or in-town processors are also covered by the prohibition."); *Dean Milk Co.*, 340 U.S. at 354 n.4, 71 S.Ct. 295 (holding that it is "immaterial that Wisconsin milk from outside the Madison area is subjected to the same proscription as that moving in interstate commerce"); *Cloverland-Green Spring Dairies, Inc. v. Penn. Milk Mktg. Bd.*, 298 F.3d 201, 214 (3d Cir. 2002) (noting that a statute may be invalid under the dormant Commerce Clause "if it favors only a single or finite set of businesses") (internal citations and quotations omitted).

In a variant on the Secretary's theme that "the Act treats all newcomers equally," the Secretary emphasizes that all "newcomers" must file an application for a certificate, even though only the opposed pharmacies must go through "the whole nine yards" of the administrative process. This argument misconceives the fundamental

flaw in the Act. The Act and accompanying regulations permit the Secretary to reject an application on the ground that a particular area of Puerto Rico is saturated with existing pharmacies. The result of this authority is that the Secretary protects the mostly local group of existing pharmacies from competitive pressure. That the Secretary subjects all newcomers to this discriminatory scheme does not ameliorate the constitutional infirmity.

Our conclusion is also unaffected by the fact that a few of the existing pharmacies when the Act was passed (and now) are owned by out-of-Commonwealth interests. Holding otherwise would be tantamount to saying that a favored group must be *entirely* in-state for a law to have a discriminatory effect on commerce. The Secretary cites no authority for this proposition, and our precedent suggests otherwise.

In *Nat'l Revenue Corp. v. Violet*, 807 F.2d 285 (1st Cir. 1986), we considered a dormant Commerce Clause challenge to a Rhode Island statute providing that only members of the Rhode Island bar could engage in third-party debt collection. Rhode Island defended the law by arguing that it applied evenhandedly because it excluded all debt collection companies from operating within its borders. *Id.* at 290. We rejected this argument because the statute "effectively bars out-of-staters from offering a commercial service . . . and confers the right to provide th[e] service . . . upon a class largely composed of Rhode Island citizens" (i.e., members of the Rhode Island bar). *Id.* Even though some members of the Rhode Island bar were from outside

of Rhode Island,[6] we concluded that the statute discriminated against commerce because it favored a class comprised *mostly* of Rhode Island interests. *See Nat'l Revenue*, 807 F.2d at 290. So too here. While a few out-of-Commonwealth pharmacies benefit from the Act, the vast majority of favored pharmacies are local concerns.

Finally, we disagree with the Secretary's suggestion that this case is controlled by *Exxon Corp. v. Governor of Md.*, 437 U.S. 117 (1978). In *Exxon*, the Court considered the validity of a Maryland statute prohibiting refiners of petroleum from operating retail service stations within Maryland. *Id.* at 120. The Court rejected the refiners' dormant Commerce Clause challenge because the statute did not affect the right of only out-of-state entities to compete in the Maryland market; rather, all independent dealers (in and out-of-state) were permitted to compete and *all* refiners were excluded. *See id.* at 127. As the Court explained: "While the refiners will no longer enjoy their same status in the Maryland market, in-state independent dealers will have no competitive advantage over out-of-state dealers. The fact that the burden of a state regulation falls on some interstate companies does not, by itself, establish discrimination against interstate commerce." *Id.* at 127, 98 S.Ct. 2207.

This case is distinguishable because, as we have explained, the Act favors the largely local group of established pharmacies over similarly-situated out-of-Commonwealth

---

[6] States are not permitted to limit bar entry to their own citizens. *See Supreme Court of N.H. v. Piper*, 470 U.S. 274, 283 (1985).

pharmacies seeking to open new stores. Unlike *Exxon*, where the Court expressed confidence that the only result of the statute would be to "cause some business to shift from one interstate supplier to another," the statistics in this case strongly suggest that the Act helps to perpetuate local dominance of the Puerto Rico pharmacy market. *Id.* at 128; *see also supra* at 12-13. The Act does not burden a particular firm, or subgroup of firms, but rather affects *every* pharmacy seeking to open in an area of Puerto Rico where an established pharmacy already operates.

We thus find that, on balance, the Act, though facially neutral, discriminates against interstate commerce. This conclusion, however, does not end our inquiry. "When discrimination against commerce . . . is demonstrated, the burden falls on the State to justify it both in terms of the local benefits flowing from the statute and the unavailability of nondiscriminatory alternatives adequate to preserve the local interest at stake." *Hunt v. Wash. Apple Adver. Comm'n*, 432 U.S. 333, 353 (1977). The only justification offered by the Secretary for the Act is that it "seeks to encourage in-state and out-of-state [interests] alike to establish pharmacies in [underserved] geographical areas."

There is no dispute that the Commonwealth has a legitimate interest in encouraging pharmacies to locate in all parts of Puerto Rico. But, as the parties' experts testified, the certificate requirement cannot reasonably be thought to advance this purpose. Pharmacies seek to operate in areas where they can turn a profit. The refusal to grant a proposed pharmacy market entry at its desired location will not encourage the proposed pharmacy to relocate to an underserved area (unless the government

provides other incentives for it to do so). Presumably areas are underserved because pharmacies have determined that these locations are unlikely to be profitable. For this reason, the denial of a certificate request is likely to lead a pharmacy to seek to open in another potentially profitable (and therefore probably already served) area or to withdraw from the Puerto Rico market entirely. As the Fourth Circuit explained in a similar case, "the goal of providing universal service at reasonable rates may well be a legitimate state purpose, but restricting market entry does not serve that purpose." *Medigen of Ky., Inc. v. Pub. Serv. Comm'n of W. Va.*, 985 F.2d 164, 167 (4th Cir. 1993) (invalidating, on dormant Commerce Clause grounds, a statute requiring transporters of medical waste to obtain a certificate of necessity and convenience and authorizing the state agency to deny such certificates if "existing services . . . [are] reasonably efficient and adequate").

IV. Conclusion

For the foregoing reasons, 24 L.P.R.A. §§ 334 *et seq.*, as enforced by the Secretary of Health for the issuing of certificates of necessity and convenience to retail pharmacies, is invalid under the dormant Commerce Clause. Accordingly, we ***reverse*** the district court's judgment and ***remand*** for further proceedings consistent with this opinion.

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF PUERTO RICO

Walgreen Co., et al.,

Plaintiffs,

v.

John V. Rullan,
Secretary of the Puerto Rico
Department of Health,

Defendant.

Civ. No. 00-1227 (HL)

OPINION AND ORDER

(Filed Sep. 8, 2003)

Before the Court are both Plaintiffs' and Defendant's Motions for Summary Judgment (See Dkts. 115 and 122, respectively), and their Oppositions (See Dkts. 127 and 126, respectively). Plaintiffs are Walgreen Company and two wholly owned subsidiaries operating in Puerto Rico (collectively "Walgreens"). Plaintiffs bring this action pursuant to 42 U.S.C.A § 1983[1] against John V. Rullan, Puerto Rico's Secretary of Health (the "Secretary").[2] Walgreens challenges the regime which is applied in Puerto Rico to the opening and relocation of pharmacies. The specific provisions are sections 334 to 334j of Puerto Rico's Title 24 and the supporting regulations (the "CNC Act").

[1] 42 U.S.C.A § 1983 (2003).

[2] The original Defendant was Rullan's predecessor at the Department of Health. Once Rullan took office, he substituted his predecessor as a defendant in this action. See Fed. R. Civ. P. 25(d)(1).

Under this regime, a party seeking to open or relocate a pharmacy must first obtain a Certificate of Necessity and Convenience ("CNC") from the Secretary of Health. 24 P.R. Laws Ann. §§ 334 & 334a (1999). The law empowers the Secretary to develop criteria for the issuing of a CNC. The factors to be considered include any "long-term service development plan" of the party seeking the CNC; the current and projected needs of the population to be served by the pharmacy; the percent of the population of the area which would be served by the pharmacy; the current status of the "health system operating in the area"; and the possible existence of alternatives. *Id.* § 334b.

The Secretary is also responsible for establishing a procedure for evaluating CNC applications. *Id.* § 334f-2. Under this procedure, a party must first submit a letter to the Department of Health stating that it has an interest in seeking a CNC. The party must then file its application. Once the application is submitted, the Department of Health publishes notices of the application in area newspapers and sends letters to pharmacies in the affected area of the application. The existing pharmacies then submit any objections they may have to the proposed action. Afterwards, the Department of Health holds an administrative hearing, at which both the applicant and any objecting pharmacies may submit evidence and expert testimony on, among other things, whether the existing pharmacies are already adequately serving the affected area. After the administrative decision is issued, any disgruntled party may move for reconsideration and seek judicial review to Puerto Rico's Circuit Court of Appeals and Supreme Court.

The Court held Oral Arguments on June 9, 2003 on this matter. During Oral Arguments, the parties agreed to

waive the bench trial for this case and requested that the Court issue a ruling based on the parties' respective motions for summary judgment. These motions properly brief the Court on their respective issues. The Court consented to the parties' request, and the Court is now ready to rule.

I. PROCEDURAL HISTORY

This civil action was filed on February 24, 2000. On April 17, 2000, the Secretary filed a Motion to Dismiss duly opposed by Walgreens.[3] On September 28, 2001, this Court issued an Opinion and Order[4] dismissing Walgreens' claim that the CNC law and regulations violate, on their face, the dormant Commerce Clause. Upon dismissing this claim, the Court noted that Walgreens' remaining claims challenged the application of the CNC Act and its regulations on substantive due process and Commerce Clause grounds. On October 18, 2001, Walgreens moved for reconsideration of the Court's Opinion and Order and filed an Amended Complaint where it allegedly supplements the averments made in its original complaint and clarifies the basis of its facial challenge to the CNC Act.[5]

Subsequent to the Court's opinion, on February 5, 2002, the Puerto Rico Supreme Court issued its decision in *Asociacion de Farmacias de la Comunidad v. Dep't of Health*, where it invalidated Regulation 89 and reinstated Regulation 56 as the basis for processing CNC petitions by the Secretary of Health. *See Id.*, 2002 TSPR 13, 2002 WL

---

[3] See Dkts. 5 and 8.

[4] See Dkt. 57.

[5] See Dkts. 58, 59 and 138 at 2.

206999 (Feb. 5, 2002); *Asociacion de Farmacias de la Comunidad v. Dep't of Health*, 2002 TSPR 69, 2002 WL 1159514 (May 23, 2002). The Supreme Court found that Regulation 89 did not provide specific standards to guide the Secretary's discretion and therefore, the regulation constituted an invalid delegation of legislative authority. In response, the Court revived Regulation 56 prospectively for new CNC applications. According to the Secretary, he is currently in the process of enacting a new Regulation to replace Regulation 89.[6]

On March 27, 2002, the Court ordered Plaintiffs to further amend the complaint in the wake of the Puerto Rico Supreme Court's decision in *Asociacion de Farmacias de la Comunidad*, and denied Plaintiffs' October 18, 2001 motion to reconsider as moot.[7] Notwithstanding, Walgreens understood its that its Amended Complaint effectively reinstated its facial Commerce Clause challenge to the CNC Act.[8] Moreover, on October 21, 2002, the Secretary filed a motion to dismiss after Walgreens' Amended Complaint.[9] It appears that the Court's order mooting Plaintiffs' motion for reconsideration has confused the parties as to the status of Walgreens' facial challenge to the CNC Act. Walgreens asserts that if its understanding is incorrect, then it reasserts its arguments set forth in its motion for reconsideration. In light of the present confusion, and given that both parties have properly briefed the Court on all claims made in the Second

---

[6] See Dkts. 122 at 3.

[7] See Dkt. 68.

[8] See Dkt. 138 at 3.

[9] See Dkt. 99.

Amended Complaint, the Court will address the facial Commerce Clause claim in resolving this case.

II. FACTS

The following material facts are undisputed by the parties:

1. Plaintiff Walgreens, a corporation duly incorporated under the laws of Illinois with its principal place of business in Illinois, is a leading drugstore retailer in the United States and operates approximately 4000 drugstores in 43 states and in Puerto Rico.[10]

2. Sales of prescription medicines represent approximately half of the sales in Walgreens' drugstores, both nationally and in Puerto Rico.[11]

3. Defendant John V. Rullan is the Secretary of Health of Puerto Rico and is the executive and administrative officer exercising full authority over the Health Department's operations. Pursuant to 20 P.R. Laws Ann. § 383, the Secretary's duties include the enforcement of all laws which relate to the establishment and supervision of pharmacies in Puerto Rico, 24 P.R. Laws Ann. §§ 334, *et seq.* (the "CNC Act").

4. Puerto Rico's CNC Act grew out of the U.S. government's efforts to influence the regulation of the health care industries by the states. In the 1970's Congress enacted legislation that required states to adopt certificate of need regulations[12] in order to maintain

---

[10] See Dkt. 115, Exhibit 1.

[11] See Dkt. 115, Exhibits 1 and 2.

[12] What the Puerto Rico CNC Act calls a "certificate of necessity and convenience" is what is commonly called a "certificate of need" or "CON" in other U.S. jurisdictions. See Dkt. 115, Exhibit 4 at 22.

eligibility for federal financial assistance in the health care area. The purpose of this federal law was to control the spiraling cost of health care.[13] Congress thought that market forces alone would not check "overinvestment" in expensive, specialized health care facilities.[14]

5. In 1975, Puerto Rico adopted the CNC Act, modeled on the federal health care legislation then in force, in order to qualify for federal health care funding. The federal legislation never applied to pharmacies.[15]

6. In 1979, Puerto Rico amended the CNC Act, and added pharmacies to the definition of "health facilities" to which the CNC Act applied.[16]

7. A party interested in establishing a new pharmacy or relocating an existing pharmacy in Puerto Rico must petition the Health Department for a Certificate of Necessity and Convenience ("CNC").[17]

8. The CNC Act defines a CNC as "[a] document issued by the Secretary of Health authorizing a person to carry out any of the activities covered by sections 334-334j of this title, certifying that the same is necessary for the population it is to serve and that it will not unduly affect the existing services, thus contributing to the orderly and adequate development of health

---

[13] See Dkt. 115, Exhibit 3 at 7.

[14] See Dkt. 115, Exhibit 3, Sager Report at 2-7. The Secretary's expert witness did not quarrel with Prof. Sager's analysis and agreed that it explained the decision of the Puerto Rico legislature to enact the CNC Act in 1975. See Dkt. 115, Exhibit 4, Ramirez Dep. at 77-80.

[15] See Law No. 2 of November 7, 1975, 24 P.R. Laws Ann. §§ 334, *et seq*; Exhibit 4.

[16] See Law No. 189 of July 26, 1979, which amended the CNC Act. 24 P.R. Laws Ann. §§ 334, *et seq*.

[17] See 24 P.R. Laws Ann. § 334a.

services in Puerto Rico." The CNC Act provides authority to the Secretary to authorize the establishment, relocation and the operation of "Health Facilities." A pharmacy is a health care facility as that term is currently defined under the CNC Act.[18]

9. In 1986, Congress repealed the 1974 legislation that mandated state implementation of the certificate of need process. Pub. L. No. 99-60, § 701, 100 Stat. 3743, 3799 (1986). However, the CNC Act remains the law in Puerto Rico, and Puerto Rico remains the only jurisdiction in the United States to apply its certificate of need law to pharmacies.[19]

10. In 1986, the Health Department adopted Regulation 56 which established both a process for seeking CNCs and detailed substantive criteria to guide the Secretary's CNC determinations.[20]

11. On October 20, 1997, the Health Department promulgated Regulation 89 to replace Regulation 56. Regulation 89 eliminated many of the detailed substantive criteria for granting CNCs that Regulation 56 had established. Instead, the new regulation articulated general criteria for approval of CNCs that largely tracked the criteria set forth in the CNC Act itself.[21]

12. On February 5, 2002, the Puerto Rico Supreme Court invalidated Regulation 89 and reinstated Regulation 56 as the basis for processing CNC petitions by the Secretary of Health. *See Asociacion de Farmacias de la Comunidad v. Dep't of Health*, 2002 TSPR 13, 2002 WL 206999 (Feb. 5, 2002); *Asociacion de Farmacias*

---

[18] See 24 P.R. Laws Ann § 334(d) and (e).

[19] See Dkt. 115, Exhibit 1.

[20] See Dkt. 115, Exhibit 6.

[21] See Dkt. 115, Exhibit 7.

de la Comunidad v. Dep't of Health, 2002 TSPR 69, 2002 WL 1159514 (May 23, 2002).

13. An applicant or proponent must first submit a letter to Secretary advising the Health Department of his or her interest in filing a CNC petition to establish or relocate a pharmacy. Within thirty (30) days of such letter, the proponent must file the application for the CNC.[22]

14. After the Department of Health receives the CNC application, it publishes a notice in a widely read newspaper announcing to the public the proponent's CNC application. It also mails a letter to all of the pharmacies within the service area of the proposed pharmacy (or the new proposed pharmacy site) notifying them of the proponent's CNC application. Within fifteen (15) days of being notified, the pharmacies interested in opposing the proponent's application must send a letter to the proponent and to the Department of Health stating their opposition and/or interest in participating in the administrative hearing to be held concerning the proponent's CNC application.[23]

15. Once this process is completed, the administrative file is transferred to the Hearings Division of the Health Department for scheduling of an administrative hearing. The hearing is often delayed if either the applicant or any opposing pharmacies seek discovery.[24]

16. At the administrative hearing, the proponent, as well as the opposing pharmacies, present expert testimony and other evidence in support of their respective positions. After the close of evidence, each party submits a

---

[22] See Dkt. 115, Exhibit 6.

[23] See Id.

[24] See Dkt. 115, Exhibits 6 and 8.

proposed report and recommendation setting forth findings of fact and conclusions of law for the hearing examiner's consideration. Upon completion, the hearing examiner's findings and conclusions are sent to the parties and to the Secretary for a final decision which is also communicated to the parties.[25]

17. If the proponent or any of the opposing pharmacies is dissatisfied with the Secretary's decision, the dissatisfied party can request reconsideration or seek judicial review of the Secretary's decision by the Puerto Rico Circuit Court of Appeals, and subsequently, the Supreme Court. Appellate review may add an additional year (in some cases several years) to the CNC process.[26]

18. Puerto Rico is the only U.S. jurisdiction to require a CNC to open a new pharmacy.[27]

19. At the time of the amendment of the CNC Act to add pharmacies, Walgreens had twelve (12) pharmacies operating in Puerto Rico and was poised to expand its operations on the Island.[28]

20. Although the CNC Act on its face imposes administrative burdens on every pharmacy seeking to expand its operations in Puerto Rico, the Asociacion Farmacias de Comunidad de Puerto Rico ("Asociacion"), the trade association of local pharmacies in Puerto Rico, has consistently supported the application of the CNC Act to pharmacies. Membership in the Asociacion is limited to "community pharmacies or chains in which majority shareholders are residents of Puerto

---

[25] See Id; Exhibit 9.

[26] See Id.

[27] See Dkt. 115, Exhibits 1 and 4.

[28] See Dkt. 115, Exhibit 1.

Rico." *Walgreen Co. v. Feliciano*, No. 00-2012 (1st Cir. Mar. 28, 2001).[29]

21. Prescription drug price information is available to consumers. It is the policy of Walgreens' pharmacies to always respond to consumer inquiries concerning prescription drug prices and Walgreens pharmacies frequently receive calls from consumers asking about the prices for particular drugs.[30]

22. Retail pharmacies in Puerto Rico compete with each other with respect to non-price aspects of their operation such as location, hours of operation, range of prescription and non-prescription products, parking facilities, and quality of service.[31]

23. According to the Statement of Purpose that accompanied the CNC Act, the Act has three objectives: (1) to satisfy the health needs of the population; (2) to reduce medical and hospital costs; and (3) to assure the availability of health services in unattended regions.[32]

III. DISCUSSION

A. Application of the CNC Act to Retail Pharmacies – Due Process Claim

Walgreens first contention is that the application of the CNC Act to retail pharmacies does not advance any legitimate public purpose. Any consideration of the CNC Act's constitutionality must start with establishing the

---

[29] See also Dkts. 115, Exhibit 1.

[30] See Dkt. 115, Exhibit 1.

[31] See Dkt. 115, Exhibits 1, 3, and 14(b).

[32] See, Law No. 2 of November 7, 1975, "Leyes y Resoluciones de Puerto Rico", Part 2, Vol. 1975 at 1010-1013; see also Dkt. 115, Exhibit 15.

appropriate level of judicial scrutiny. *Montalvo-Huertas v. Rivera-Cruz*, 885 F.2d 971, 976 (1st Cir. 1989).

The Supreme Court has developed a tripartite rubric for evaluating challenges to legislation under the Equal Protection and Due Process clauses. *Kittery Motorcycle, Inc. v. Rowe*, 320 F.3d 42 (1st Cir. 2003). When a statute burdens certain "fundamental rights" (*e.g.*, voting rights or the right to interstate travel) or distinguishes between people on the basis of certain "suspect characteristics" (*e.g.*, race or national origin), the statute is subject to "strict scrutiny." *Zablocki v. Redhail*, 434 U.S. 374, 388, 98 S.Ct. 673 (1978); *see also Atty. Gen. of N.Y. v. Soto-Lopez*, 476 U.S. 898, 906, 106 S.Ct. 2317 (1986) (right to interstate travel); *Shaw v. Reno*, 509 U.S. 630, 643-45, 113 S.Ct. 2816 (1993) (racial classifications). To survive strict scrutiny, the statute must serve a compelling state purpose and be narrowly tailored to achieving that purpose. *Zablocki*, 434 U.S. at 388. The Supreme Court has identified other classifications, such as illegitimacy, which are less "suspect" and thus subject to a less exacting level of scrutiny, often characterized as "intermediate" scrutiny. In such cases, the government must demonstrate that the challenged classification is "substantially related to an important government objective." *Clark v. Jeter*, 486 U.S. 456, 461, 108 S.Ct. 1910 (1988).

All other regulations, including the statute under review in this case, are subject to the third and least exacting tier of scrutiny, "rational basis" review, requiring only that the regulation bear some rational relation to a legitimate state interest. *Romer v. Evans*, 517 U.S. 620, 632, 116 S.Ct. 1620 (1996). "Social and economic legislation . . . that does not employ suspect classifications or impinge on fundamental rights must be upheld . . . when

the legislative means are rationally related to a legitimate government purpose." *Hodel v. Indiana*, 452 U.S. 314, 331, 101 S.Ct. 2376 (1981).

The Court starts with the presumption of the constitutional validity of a state law.[11] *See Missouri v. Jenkins*, 515 U.S. 70, 112, 115 S.Ct. 2038 (1995) (O'Connor, J., concurring); *City of Cleburne v. Cleburne Living Center, Inc.*, 473 U.S. 432, 440, 105 S.Ct. 3249 (1985). Under the standard of review applicable to this case, that Court's role demands deference and restraint. *See FCC v. Beach Communications, Inc.*, 508 U.S. 307, 313-14, 113 S.Ct. 2096 (1993) ("This standard of review is a paradigm of judicial restraint."). "Even foolish and misdirected provisions" will be upheld under this test. *Kittery Motorcycle*, 320 F.3d at 47 (citing *Craigmiles v. Giles*, 312 F.3d 220, 223-24 (6th Cir. 2002)). In order to defeat Walgreens' claim, the Secretary need only articulate some "reasonably conceivable set of facts" that could establish a rational relationship between the challenged laws and the government's legitimate ends. *Kittery Motorcycle*, 320 F.3d at 47 (citing *Montalvo-Huertas*, 885 F.2d at 978). These proffered facts "need not be supported by an exquisite evidentiary record," *Craigmiles*, 312 F.3d at 224, nor by any evidentiary record at all. *Heller v. Doe*, 509 U.S. 312, 320, 113 S.Ct. 2637 (1993) ("A State, moreover, has no obligation to produce evidence to sustain the rationality of a statutory classification."); *Beach Communications*, 508 U.S. at 315, 113 S.Ct. 2096 ("[A] legislative choice is not

---

[11] Puerto Rico is treated as a state for purposes of the Due Process Clause of the Fourteenth Amendment. *Mundo-Rios v. Vizcarrondo-Irizarry*, 228 F.Supp.2d 18, 28 (D.P.R. 2002) (citing *Calero-Toledo v. Pearson Yacht Co.*, 416 U.S. 663, 668-69 n.5 (1974)).

subject to courtroom factfinding and may be based on rational speculation unsupported by evidence or empirical data.").

1. Application of Rational Basis Test

According to the Statement of Purpose that accompanied the CNC Act, the Act has three objectives: (1) to satisfy the health needs of the population; (2) to reduce medical and hospital costs; and (3) to assure the availability of health services in unattended regions.[34] In his Motion for Summary Judgment, the Secretary does not address whether the second objective applies to the CNC Act's regulation of pharmacies. The Secretary only addresses the first and third objectives of the Act. Specifically, he states, "the CNC Act seeks to regulate the licensing of prescription pharmacies . . . so that they are geographically distributed to satisfy the health needs of the population and are not concentrated in a given geographic area."[35] The Court will therefore analyze whether application of the CNC Act to pharmacies is rationally related to the government's purpose of encouraging the establishment of pharmacies in unattended areas of Puerto Rico.

---

[34] See, Law No. 2 of November 7, 1975, "Leyes y Resoluciones de Puerto Rico", Part 2, Vol. 1975 at 1010. This statement of purpose was part of the 1975 Puerto Rico statute that created the CNC scheme. As enacted in 1975, the Act did not apply to retail pharmacies. Retail pharmacies were added in 1979 by an amendment that had no statement of purpose and as to which there appears to be no legislative history. See Dkt. 115 at 14.

[35] See Dkt. 122 at 6.

Walgreens argues that there is no rational support for the CNC regulatory scheme in which pharmacies established in an area where a proponent seeks to operate are provided an opportunity to comment and oppose the proponent's request. According to Walgreens, if a pharmacy is denied a CNC to establish in an area where the applicant perceives a desirable business opportunity, the applicant will not, as a consequence of the denial, opt to establish in an area where there is no such opportunity. Walgreens further argues that the CNC does nothing to create business opportunities in "underserved" areas such as by providing tax incentives or subsidies for pharmacies that are willing to establish in the poorest neighborhoods or in rural areas where demand is low.

Plaintiffs contend that the tenuous relation between the CNC Act and the goal of promoting pharmacies in "underserved" communities is further apparent given the undisputed evidence that (1) there are at least as many pharmacies per capita in Puerto Rico as there are on the mainland,[36] (ii) Puerto Ricans are highly mobile, as reflected in the number of automobiles per household,[37] and (iii) consumers in Puerto Rico can obtain prescription drugs by mail order and via internet, as well as from more than 900 private pharmacies on the island.[38]

Although Walgreens has presented a solid case demonstrating the statute's inefficiency, imperfections and overall questionable wisdom, Walgreens faces an uphill

---

[36] See Dkt. 115, Exhibit 3, Sager Report at 9 and Exhibit 5, Freyre Report at 11-13.

[37] See Dkt. 115, Exhibit 5, Freyre Report at 12.

[38] See Dkt. 15, Exhibit 5, Freyre Report at 12-13.

battle. Walgreens argues that the Secretary has failed to support his contention that the CNC Act in any way helps promote the goal of encouraging the establishment of pharmacies in "underserved" areas. However, the Secretary only needs to articulate some "reasonably conceivable set of facts" that establish a rational relationship between the law and the proffered objective. *Kittery Motorcycle*, 320 F.3d at 47. Moreover, these facts "need not be supported by any evidentiary record at all." *Id.* (citing *Heller*, 509 U.S. at 320). In fact, the Supreme Court has stated, "[A] legislative choice is not subject to courtroom factfinding and may be based on rational speculation unsupported by evidence or empirical data." *Beach Communications*, 508 U.S. at 313-14.

The record shows that Walgreens has not been denied access to areas where there are no established pharmacies. In fact, one hundred percent (100%) of Walgreens' unopposed CNC applications have been granted by the Department of Health. Only pharmacies located in a one-mile radius from the proposed pharmacy can oppose the application. Hence, the Secretary treats areas lacking a pharmacy within a one-mile radius as "underserved." Given this scenario, it is reasonable for the Commonwealth to conclude that a pharmacy may opt to establish in an "underserved" location. If virtually all CNC petitions are granted if unopposed, then a potential pharmacy has a strong incentive in seeking an "underserved" location. Plus, the pharmacy will save a significant amount of time and money in the application process.

Still, Walgreens questions whether any "underserved" communities even exist today in Puerto Rico, and the Secretary's own expert fails to illustrate whether the geographic distribution of pharmacies in Puerto Rico is

inequitable. Nevertheless, the Court must be cautious with this line of analysis. As the First Circuit has stated, "evaluating the continued need for, and suitability of, legislation . . . is exactly the kind of policy judgment that the rational basis was designed to preclude." *Montalvo-Huertas*, 885 F.2d at 977 (citing *Ferguson v. Skrupa*, 372 U.S. 726, 731, 83 S.Ct. 1028, 1032 (1963)). Moreover, "by suggesting that a statute must be rationally related to the purpose which actually motivated its enactment, [plaintiffs] are in effect applying a heightened level of scrutiny." *Id.* at 978.

The CNC law, like other social or economic legislation, carries with it a presumption of rationality that can only be overcome by a clear showing of arbitrariness and irrationality. Plaintiffs must remember that the constitutional inquiry does not look to the CNC law's wisdom or questions whether the law has in fact achieved its goal. *Id.* In essence, "[a] court may only ask whether Puerto Rico's legislature 'rationally could have believed that [the CNC Act] would promote its objective.'" *Id.* (citing *Western & Southern Life Ins. Co. v. Board of Equalization*, 451 U.S. 648, 671-72, 101 S.Ct. 2070, 2084-85 (1981)). The Court finds that the Secretary has established a rational relationship between the application of the CNC Act to pharmacies and the goal of encouraging the establishment of pharmacies in "underserved" areas. While it may be true, as Walgreens argues, that a more tailored law would better serve both the public and pharmacy owners, it is not this Court's duty to pass judgment on the law's utility. If the Puerto Rico legislature has used its power unwisely, this is a matter for the voters, not the federal courts. *Montalvo-Huertas*, 885 F.2d at 982. Under rational basis review, this Court is constrained to conclude that the

application of the CNC Act to pharmacies does not run afoul of the Constitution's Due Process Clause.

B. Dormant Commerce Clause Challenge

Walgreens maintains that the CNC Act violates the dormant Commerce Clause on three grounds. First, it claims that the CNC Act facially discriminates against interstate commerce by erecting significant procedural and substantive barriers to entry into the retail pharmacy business for the express purpose of protecting existing pharmacies from competition. Second, Walgreens argues that the practical effect of the application of the CNC Act to pharmacies has been discrimination against national pharmacy chains.[39] Third, they assert that even if the application of the CNC Act did not discriminate against national pharmacy chains, the Act's erection of entry barriers imposes burdens on interstate commerce that are not outweighed by local benefits, and therefore violates the dormant Commerce Clause.

The Commerce Clause states: "The Congress shall have Power . . . To regulate Commerce . . . among the several States. . . ." U.S. CONST. ART. I, § 8 CL. 3. This affirmative grant of authority to Congress also encompasses an implicit "dormant" limitation on the authority of the states to enact legislation affecting interstate commerce.[40] *See Healy v.*

---

[39] Throughout this opinion the Court will refer to non-local pharmacy chains (*i.e.*, chains originating outside of Puerto Rico) as national pharmacy chains, mainland pharmacies or out-of-state interests. The national pharmacy chains in Puerto Rico include Walgreens, K-Mart and Wal-Mart.

[40] Puerto Rico is treated as a state for purposes of the Dormant Commerce Clause. *Used Tire Int'l, Inc. v. Diaz-Saldana*, 155 F.3d 1, 4

(Continued on following page)

Beer Inst., 491 U.S. 324, 326, 109 S.Ct. 2491 (1989). At the same time, the Supreme Court has long recognized that "in the absence of conflicting legislation by Congress, there is a residuum of power in the state to make laws governing matters of local concern which nevertheless in some measure affect interstate commerce or even, to some extent, regulate it." *So. Pac. Co. v. Arizona, ex rel. Sullivan*, 325 U.S. 761, 767, 65 S.Ct. 1515 (1945). While this "residuum" is particularly strong when a state acts in the interest of health and consumer protection, a finding that it has acted to further these matters of legitimate concern does not automatically end the inquiry. *Philip Morris, Inc. v. Reilly*, 267 F.3d 45, *13 (1st Cir. 2001) (citing *Hunt v. Wash. State Apple Adver. Comm'n*, 432 U.S. 333, 350, 97 S.Ct. 2434 (1977)). Overall, the core purpose of the dormant Commerce Clause is to prevent states and their political subdivisions from promulgating protectionist policies. *Houlton Citizens' Coalition v. Town of Houlton*, 175 F.3d 178, 185 (1st Cir. 1999) (citing *Camps Newfound/Owatonna v. Town of Harrison*, 520 U.S. 564, 578, 117 S.Ct. 1590 (1997)).

The First Circuit has noted that the prohibitions imposed upon state regulations by the dormant Commerce Clause fall into three general categories. *Philip Morris*, 267 F.3d at *13; *Pharm. Research and Mfrs. of Am. v. Concannon*, 249 F.3d 66, 79 (1st Cir. 2001). To determine whether a statute violates the dormant Commerce Clause, courts apply different levels of analysis, depending on the

---

n.2 (1st Cir. 1998); *Trailer Marine Transp. Corp. v. Rivera Vazquez*, 977 F.2d 1, 7 (1st Cir. 1992); *Nat'l Pharmacies, Inc. v. De Melecio*, 51 F.Supp.2d 45, 56 n.21 (D.P.R. 1999), *aff'd*, 221 F.3d 235 (1st Cir. 2000).

effect and reach of the legislation. *Concannon*, 249 F.3d at 79.

First, a state statute is a per se violation of the Commerce Clause when it has an "extraterritorial reach." *Philip Morris*, 267 F.3d at *13; *Concannon*, 249 F.3d at 79 (citing *Healy*, 491 U.S. at 336). Hence, a state statute is invalid when it regulates commerce occurring wholly outside the state's borders or when it has a practical effect of requiring out-of-state conduct to be carried on according to in-state terms. *Id.* A statute will have an extraterritorial reach if it necessarily requires out-of-state commerce to be conducted according to in-state terms. *Concannon*, 259 F.3d at 79.

Second, if a state statute discriminates against interstate commerce, the court applies strict scrutiny. If the statute discriminates against out-of-state commerce, or its effect is to favor in-state economic interests over out-of-state interests, it will be invalid unless the state can "show that it advances a legitimate local purpose that cannot be adequately served by reasonable nondiscriminatory alternatives." *Philip Morris*, 267 F.3d at *13 (citing *Or. Waste Sys., Inc. v. Dep't of Envtl. Quality of Or.*, 511 U.S. 93, 100-01, 114 S.Ct. 1345 (1994) (alteration and internal quotation marks omitted)); *see also Bacchus Imports, Ltd. v. Dias*, 468 U.S. 263, 270, 104 S.Ct. 3049 (1984) (indicating that a finding of discriminatory purpose or discriminatory effect can constitute economic protectionism subjecting the state statute to a "stricter level of invalidity").

Lastly, the Court applies a lower level of scrutiny if the state statute does not discriminate but has incidental effects on interstate commerce. *Philip Morris*, 267 F.3d at *13; *Concannon*, 249 F.3d at 80. In this situation, the *Pike*

balancing test is applied. *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142, 90 S.Ct. 844 (1970). Under this test, "Where the statute regulates evenhandedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits." *Id.*

Walgreens' claims fall into the second and third categories of prohibitions imposed upon state regulations by the dormant Commerce Clause.[41] Walgreens maintains that the CNC Act discriminates against interstate commerce on its face and in practical effect, and therefore, is per se violative of the dormant Commerce Clause. Walgreens argues that the Act erects significant procedural and substantive barriers to entry into the retail pharmacy business for the express purpose of protecting existing pharmacies from competition. It further contends that the practical effect of the application of the CNC Act to retail pharmacies has been discrimination against national pharmacy chains. Walgreens next argues that even if the application of the CNC Act did not discriminate against national pharmacy chains, the Act's erection of entry barriers imposes burdens on interstate commerce that are not outweighed by local benefits, and therefore fails the *Pike* balancing test.

---

[41] Walgreens does not argue that the CNC Act is per se invalid because it regulates conduct beyond Puerto Rico.

1. Strict Level of Scrutiny: Discriminatory Statute

a) Facial Discrimination Challenge

The Court will first address the question of whether the challenged statute discriminates on its face against interstate commerce (as opposed to regulating commerce evenhandedly with only incidental effects on interstate commerce). *Houlton*, 175 F.3d at 185; *C & A Carbone, Inc. v. Town of Clarkstown*, 511 U.S. 383, 390, 114 S.Ct. 1677 (1994). A statute that discriminates on its face against interstate commerce and in favor of local businesses is per se invalid, unless the state can demonstrate, under rigorous scrutiny, that it has no other means to advance a legitimate local interest. *C & A Carbone*, 511 U.S. at 392.

Walgreens argues that the CNC Act facially violates the dormant Commerce Clause because it (i) created significant regulatory barriers to entry into the retail pharmacy market in Puerto Rico but relieved the large, and almost entirely local, group of existing pharmacies from the obligation to meet the same standards as would-be market entrants, and (ii) precludes the grant of a CNC without an administrative certification that existing pharmacies will not be "unduly affect[ed]" by the proposed competition. Walgreens asserts that in no other U.S. jurisdiction are there significant regulatory barriers to entering the retail pharmacy market.[42] In Puerto Rico it is not enough that a business obtain space, purchase equipment and inventory, hire licensed personnel and obtain a pharmacy license, a business must also obtain a CNC.

---

[42] See Dkt. 115, Exhibit 1, Tovian St. ¶ 15.

Walgreens argues that this expensive and time-consuming process is a significant barrier to entry.

Although Walgreens complains of the inefficient, time-consuming, and complicated procedure that it must go through to receive the permit, any local economic interest seeking to obtain a CNC must also jump through the same bureaucratic hoops. Still, Walgreens maintains that the Act is no less discriminatory because Puerto Rico businesses that seek to establish a competing pharmacy face the same obstacles. Walgreens cites the seminal case *C & A Carbone, Inc. v. Clarkstown*, 511 U.S. 383 (1994), in support of its argument. In *C & A Carbone*, the Court held that a town's ordinance requiring that all waste generated in the town be processed by a particular recycling facility discriminated against interstate commerce. The Court held, "With respect to this stream of commerce, the ordinance discriminates, for it allows only the favored operator to process waste that is within the town's limits. It is no less discriminatory because in-state or in-town processors are also covered by the prohibition." *Id.* at 384. Before reaching this conclusion, the Court first found that the flow control ordinance regulated interstate commerce because it drove up the cost for out-of-state interests to dispose of their solid waste. Moreover, the ordinance excluded everyone except one local operator from processing the waste.

The case presently before this Court is clearly distinguishable from *C & A Carbone*. In contrast to the flow control ordinance of Clarkstown, the CNC Act does not deprive out-of-state businesses of access to the local market. It does not prohibit local or national pharmacy chains from establishing in Puerto Rico, nor are its economic effects interstate in reach. Although the Act

requires pharmacies to jump through several bureaucratic hoops in order to receive a permit, and this process may pose obstacles to entry in certain service areas, the Act does not preclude the establishment of competing pharmacies.

The First Circuit case *National Revenue Corp. v. Violet*, 807 F.2d 285 (1st Cir. 1986), which Walgreens cites in connection with its facial discrimination claim is similarly inapposite. The First Circuit in *National Revenue* declared a Rhode Island statute invalid on Commerce Clause grounds where it defined debt collecting as a practice of law and prohibited nonlawyers from engaging in debt collection. The Court held the statute effectively barred out-of-staters from offering a commercial service while bestowing economic benefit upon a class largely composed of Rhode Island citizens. In contrast to the CNC Act, the Rhode Island statute effectively foreclosed out-of-state debt collectors, en masse, from seeking to collect debts from Rhode Island citizens. The CNC Act does not foreclose national pharmacy chains from establishing in Puerto Rico.

The First Circuit has clearly stated that "to the extent that in-state and out-of-state bidders are allowed to compete freely on a level playing field, there is no cause for constitutional concern." *Houlton*, 175 F.3d at 188. While addressing whether a challenged ordinance discriminated on its face against interstate commerce, the First Circuit in *Houlton* held that if local legislation leaves all comers with equal access to the local market, it does not offend the dormant Commerce Clause. In the present case, the CNC Act does not exclude mainland pharmacy chains from applying for a permit. On the contrary, all interests – be they based inside or outside of Puerto Rico – must submit

to the same onerous procedures. The record contains no hint that the statute is shaped to favor local pharmacies, nor does the Act include terms that either give local pharmacies a leg up or disadvantage their out-of-state rivals. Both in-state and out-of-state applicants may apply freely to obtain a CNC, and national pharmacy chains are not reviewed any differently than local pharmacies. Accordingly, the Court finds that the CNC Act does not facially discriminate against interstate commerce.

b) Discriminatory Purpose

Walgreens next attempts to invoke the proposition that the CNC Act is invalid because it was designed with a discriminatory purpose. When it is shown that a law was enacted with a purpose to discriminate against interstate commerce, a strict scrutiny analysis is also required. *Environmental Waste Reductions, Inc. v. Reheis*, 887 F.Supp. 1534, 1558 (N.D. Ga. 1995); *see also Chemical Waste Mgmt., Inc. v. Hunt*, 504 U.S. 334, 344, 112 S.Ct. 2009 (1992) (explaining that a finding of impermissible economic protectionism may be made on the basis of a discerned discriminatory purpose).

Walgreens contends that the statute's protectionist intent is evident because the statute precludes the grant of a CNC without an administrative certification that existing pharmacies will not be unduly affected by the proposed competition. Moreover, the Act relieves an overwhelmingly local group of existing pharmacies of the obligation of meeting the same standards as newcomers. The CNC Act defines a CNC as "[a] document issued by the Secretary of Health authorizing a person to carry out any of the activities covered by sections 334-334j of this title, certifying

that the same is necessary for the population it is to serve and that it will not unduly affect the existing services, thus contributing to the orderly and adequate development of health services in Puerto Rico." 24 P.R. Laws Ann. § 334(e). When the CNC Act was amended in 1979 to include pharmacies, those pharmacies already in existence – a group that is almost entirely composed of local pharmacies[43] – were "grandfathered," *i.e.*, automatically entitled to a CNC. 24 P.R. Laws Ann. § 334g.

The fact that an overwhelming majority of the pharmacies in the island prior to 1979 were locally-owned, and this group was relieved from having to undergo the CNC application process, does not lead the Court to adduce a protectionist intent from the statute. In fact, at the time of the CNC amendment, Walgreens had twelve (12) pharmacies operating in Puerto Rico.[44] Hence, this group of Walgreens stores were also "grandfathered" – as coined by Plaintiffs – and automatically entitled to a CNC. When the CNC Act was amended to include pharmacies, the statute made no distinction between local and national pharmacies. On the contrary, the only distinction the statute makes among pharmacies are those established prior to and after October 24, 1979. In sum, Walgreens has not presented sufficient evidence to substantiate its conclusory allegation of discriminatory purpose.

---

[43] See Dkt. 115, Exhibit 5, Freyre Report at 2.

[44] See Docket 115, Exhibit 1, Tovian St. ¶ 4. According to the 1977 Census of Business, a total of 859 single unit drug stores comprised 91.2% of the total number of establishments (942). See Exhibit 5, Freyre Report at 2.

c) Discriminatory Effect

Walgreens next avers that the practical effect of the CNC Act on retail pharmacies has been discrimination against mainland pharmacy chains. When a statute's effect is to favor in-state economic interests over out-of-state interests, courts have generally struck down the statute without further inquiry. *Concannon*, 249 F.3d at 80 (citing *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 579, 106 S.Ct. 2080 (1986)). Walgreens argues that the CNC Act does not constrain the expansion of local pharmacies yet creates a significant barrier to entry for mainland retail chains. As demonstrated in Table 4 of Dr. Freyre's Report, all unopposed petitions – either from local or out-of-state pharmacies – were granted by the Secretary. The numerical differential relates to opposed petitions. According to data provided by the Department of Health, the Secretary has granted ninety percent (90%) of local pharmacy petitions when opposed, and fifty-eight percent (58%) of mainland petitions when opposed. Moreover, even when the CNC is granted, it takes considerably longer for mainland pharmacy chains to obtain their CNCs than it takes for local pharmacies.[46] Walgreens claims that such delays increase the cost of opening a pharmacy and constitute another discriminatory barrier to entry.

Although local pharmacies are granted a CNC at a much higher rate than their out-of-state counterparts, this bare fact is insufficient to establish a pattern of discrimination against non-local pharmacy chains. Plaintiffs

---

[46] On average, it takes Walgreens eight (8) months longer than the local chains El Amal/Moscoso to obtain a CNC on opposed petitions. See Dkt. 115, Exhibit 5, Freyre Report, Table 6.

provide no information regarding the reasons for the denials of the out-of-state petitions vis a vis the local petitions. For example, certain petitions may have been denied because they were defective, or they sought the establishment of a pharmacy in a service area considered highly saturated pursuant to CNC guidelines. The Court is also unaware of the reasons why the CNC petitions granted to national pharmacies undergo a longer application process than those of local pharmacies. A myriad of factors might affect the application time-line. Such factors may include the service area where the pharmacy seeks to operate, the number of pharmacies already in the area, and the ratio of the area's population per pharmacy.

Walgreens does not present sufficient evidence from which the Court can derive a pattern of discrimination that amounts to a constitutional violation. For example, Walgreens presents a Table listing the months it takes for the Department of Health to notify a decision to mainland pharmacies versus local pharmacies per municipality.[46] Although the Table lists the time-line, it provides no information regarding the dates of these applications, the service area covered by the application, or its level of saturation. This limited information is not sufficient for the Court to draw a fair comparison. Absent clearer data, the Court is unable to attribute any probative value to such numbers. In sum, the evidence presented by Walgreens is insufficient to prove that the CNC Act's effect is to favor in-state over out-of-state interests. Accordingly, the Court finds that the CNC Act's application to pharmacies does not discriminate against interstate commerce.

---

[46] See Dkt. 115, Exhibit 5, Freyre Report, Table 6.

2. Low Level of Scrutiny: Pike Balancing Test

Walgreens' final contention is that even if the application of the CNC Act did not discriminate against national pharmacy chains, the Act's erection of entry barriers imposes burdens on interstate commerce that are not outweighed by its local benefits, thus violating the dormant Commerce Clause as applied in *Pike*. This contention, which calls for the application of the *Pike* balancing test, *see Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142, 90 S.Ct. 844 (1970), "stands on uncertain legal terrain." *Grant's Dairy v. Comm'r of Maine Dep't of Agriculture*, 232 F.3d 8, 24 (1st Cir. 2000).

When a state statute regulates evenhandedly and has only incidental effects on interstate commerce, the statute will be upheld unless the burden on interstate commerce is "clearly excessive in relation to the putative local benefits." *Pike*, 397 U.S. at 142. Under *Pike*:

> If a legitimate local purpose is found, then the question becomes one of degree. And the extent of the burden that will be tolerated will of course depend on the nature of the local interest involved, and on whether it could be promoted as well with a lesser impact on interstate activities.

Id. Here, the CNC Act regulates evenhandedly and its effects on interstate commerce are only incidental. Thus, the question is one of degree: whether the burden it imposes compared to the putative local benefits is clearly excessive.

According to Walgreens, the CNC Act erects significant procedural and substantive barriers to entry into the retail pharmacy business, thereby burdening interstate

commerce. Pursuant to this theory, the statute's incidental effect on interstate commerce is that it limits the market entry of out-of-state pharmacies in certain locations on the island. The statute limits competition, and thus, the establishment of out-of-state pharmacy chains in Puerto Rico.

Walgreens cites to the Fourth Circuit case *Medigen of Kentucky, Inc. v. Public Service Comm.*, 985 F.2d 164 (1993) to support the argument that the CNC requirement is invalid under the *Pike* test. In *Medigen* an interstate transporter of infectious medical waste challenged a West Virginia requirement that such transporters obtain a certificate of convenience and necessity to operate within the state. The Court held that the burden imposed by the certification requirement on interstate commerce outweighed its local benefits. Although *Medigen* is analogous to the present case in that is involves a CNC law, the cases differ in their connection to interstate commerce. The Fourth Circuit in *Medigen* found that the CNC law burdened interstate commerce because it restricted the market entry of haulers of medical waste. Since the Plaintiffs in *Medigen* were *interstate* transporters of infectious waste, the potential burden to interstate commerce is more direct than in the present case. In fact, the district court in *Medigen* had found that the certification requirement was a "direct" regulation of interstate commerce. In contrast to the plaintiffs in *Medigen*, Walgreens is unable to make a clear showing of the CNC Act's burden on interstate commerce.

The problem with Walgreens' proffered burden is that "the [Commerce] Clause protects the interstate market, not particular interstate firms, from prohibitive or burdensome regulations." See *Philip Morris*, 267 F.3d at *16;

Concannon, 249 F.3d at 84 (citing *Exxon Corp. v. Governor of Md.*, 437 U.S. 117, 127-128 (1978)). Two recent First Circuit cases, *Phillip Morris* and *Concannon*, have both noted that when the only burden imposed on interstate commerce is an Act's possible effects on the profits of individual manufacturers, this is not sufficient to rise to a Commerce Clause burden. "The fact that a law may have 'devastating economic consequences' on a particular interstate firm is not sufficient to rise to a Commerce Clause burden." *Concannon*, 249 F.3d at 84 (citing *Instructional Sys., Inc. v. Computer Curriculum Corp.*, 35 F.3d 813, 827 (3rd Cir. 1994)). The Second Circuit has also stated that an excessive burden in relation to putative benefits is a burden on interstate commerce that is different from the burden imposed on intrastate commerce. *Brown & Williamson Tobacco Corp. v. Pataki*, 320 F.3d 200, 217 (2d Cir. 2003); *see also Gary Peake Excavating Inc. v. Town Bd. of Town of Hancock*, 93 F.3d 68 (2d Cir. 1996) ("We have explained that the 'incidental burdens' to which *Pike* refers are the burdens on interstate commerce that exceed the burdens on intrastate commerce.").

Although the CNC Act may prevent Walgreens and other out-of-state pharmacy chains from establishing a pharmacy in a particular area of Puerto Rico, the Act does not prevent out-of-state interests from operating in the island. To the contrary, there are currently around fifty (50) Walgreens pharmacies on the island.[47] Out of fifty-eight (58) CNC petitions filed by Walgreens, forty-three (43) of these have been granted.[48] Walgreens has not been

---

[47] See Dkt. 122, Secretary's Statement of Material Facts, ¶ 7.

[48] See Dkt. 115, Exhibit 5, Freyre Report, Table 3.

denied access to the Puerto Rico market, except insofar as it seeks to establish new pharmacies in a one-mile radius where there are other existing pharmacies. More importantly, the statute applies equally to all potential pharmacies, regardless of their point of origin. Local pharmacy chains must face the same onerous procedure to obtain a CNC. The Act imposes the same burden on local pharmacy chains that seek to operate on the island. Therefore, the statute does not impose burdens on interstate commerce that exceed the burdens imposed on intrastate commerce.

The Court next considers the benefits the Commonwealth seeks to secure by imposing the CNC Act. Puerto Rico has a legitimate interest in regulating its pharmacies subject to constitutional constraints. A state has a legitimate interest in promulgating regulations governing the health and safety of its citizens. *Maine v. Taylor*, 477 U.S. 131, 151, 106 S.Ct. 2440, 2454 (1986); *Houlton*, 175 F.3d at 191. Even though a statute may cause the consuming public to be injured by the loss of the high-volume, low-priced businesses, if it does not burden interstate commerce, the problem will be one as to the wisdom of the legislation, not its constitutionality. *Exxon Corp.*, 437 U.S. at 127-28. While it may be true, as Walgreens argues, that the procedures put in place by the CNC Act are inefficient, unnecessarily bureaucratic, and overly-time consuming, it is not the duty of this Court to undergo a utility analysis. Given the Act's modest burden on *interstate* commerce, the Court is unable to conclude that this burden is "clearly excessive" in relation to its *putative* local benefits. Hence, the CNC Act is not invalid under the *Pike* test.

IV. CONCLUSION

In upholding the application of the CNC Act to retail pharmacies, 24 P.R. Laws Ann. § 334 *et seq*, and supporting regulation, the Court does no more than recognize that, "under the system of government created by our Constitution, it is up to the legislatures, not courts to decide on the wisdom and utility of legislation." *Montalvo-Huertas*, 885 F.2d at 98 (citing *Ferguson*, 372 U.S. at 729). Under the rationality review accorded to this statute, the Court concludes that application of the CNC Act to pharmacies does not violate the Due Process Clause. The Court further concludes that the CNC Act does not violate the dormant Commerce Clause. Accordingly, the Court hereby **DENIES** Walgreens' Motion for Summary Judgment (Dkts. 115) and **GRANTS** the Secretary's Motion for Summary Judgment (Dkts. 122).

IT IS SO ORDERED.

San Juan, Puerto Rico, September 8th, 2003.

/s/ [Illegible]
HECTOR M. LAFFITTE
Chief U.S. District Judge

United States Court of Appeals
For the First Circuit

No. 03-2542

WALGREEN COMPANY;
WALGREENS OF SAN PATRICIO, INC.;
WALGREENS OF PUERTO RICO, INC.
Plaintiffs-Appellants,

v.

JOHN RULLAN, In his Official
Capacity as Puerto Rico Health Secretary
Defendant-Appellee.

CARMEN FELICIANO-DE-MELECIO
Defendant.

ORDER OF COURT

Before: Chief Judge Boudin,
Judges Torruella, Lipez & Howard, Circuit Judges.

Entered: June 7, 2005

The panel of judges that rendered the decision in this case having voted to deny the petition for rehearing and the suggestion for the holding of a rehearing en banc having been carefully considered by the judges of the court in regular active service and a majority of said judges not having voted to order that the appeal be heard or reheard by the court en banc,

It is ordered that the petition for rehearing and the suggestion for rehearing en banc, be denied.

BY THE COURT:

RICHARD CUSHING DONOVAN
RICHARD CUSHING DONOVAN,
CLERK

24 L.P.R.A. § 334

LAWS OF PUERTO RICO ANNOTATED
TITLE TWENTY-FOUR. Health and Sanitation
PART I. HOSPITALS, INSTITUTIONS,
AND HEALTH PROGRAMS
CHAPTER 19. Health Facilities
SUBCHAPTER III. Certificates of
Necessity and Convenience

§ 334. Definitions

For the purposes of §§ 334-334j of this title, the following words shall have the meanings set forth hereinbelow, to wit:

(a) *Secretary.* – The Secretary of Health of the Commonwealth of Puerto Rico.

(b) *Department.* – The Department of Health of the Commonwealth of Puerto Rico.

(c) *Person.* – A natural or juridical person.

(d) *Health facilities.* – Hospitals, extended care facilities, nursing care facilities, rehabilitation centers, renal disease centers, including portable hemodialysis units, centers for ambulatory surgery, home health services program, diagnosis and treatment centers, pharmacies, blood banks, clinical laboratories and radiology facilities, as defined in §§ 334-334j of this title.

(e) *Certificate of Necessity and Convenience.* – A document issued by the Secretary of Health authorizing a person to carry out any of the activities covered by §§ 334-334j of this title, certifying that the same is necessary for the population it is to serve and that it will not unduly affect the existing services, thus contributing to the

orderly and adequate development of health services in Puerto Rico.

(f) *Construction.* – Construction shall include the initiation, remodeling, expansion of the facility with the purpose of completing the construction of a health facility.

(f-a) *Relocate.* – The relocation of a health facility previously located in a specific geographical limit, place or territory. This does not include the relocation of services within the same physical structure or an adjacent one.

(g) *Hospital.* – An institution that primarily provides inpatients, by or under medical supervision, with diagnosis, treatment, care or rehabilitation services for injured, disabled or sick persons. It includes general hospitals as well as specialized hospitals.

(h) *Extended care facilities (Skilled nursing care).* – An institution that primarily provides skilled nursing care and related health services to hospitalized patients that do not require the direct medical supervision provided by a hospital for their condition.

(i) *Diagnostic and treatment center.* – An independent facility, or one operated in connection with a hospital that provides integrated health services for the diagnosis and treatment of ambulatory patients and that gives or makes available through arrangements with other health facilities, X-ray and clinical laboratory services.

(j) *Nursing care facilities.* – An institution that provides health-related care and services to physically or mentally ill persons who do not require the degree of care and treatment that a hospital or extended care facility provides.

(k) *To offer or develop a new health service.* – It shall be deemed that a person is proposing to offer or develop a new health service when he plans to undertake one of the following activities:

(1) The construction, development or establishment, or any sort of acquisition of a health facility.

(2) The addition of a health service by any facility covered by §§ 334-334j of this title that has operating expenses in excess of the limit fixed in § 334a(8) of this title, when said limit is applicable.

(l) *Rehabilitation center.* – An institution for hospitalized patients that operates for the purpose of assisting in the rehabilitation of physically or mentally disabled persons through an integrated program of medical and other services, under the supervision of specialized professional personnel.

(m) *Renal dialysis center.* – A unit of a hospital authorized to provide diagnostic, treatment and rehabilitation services to patients with chronic renal diseases. It also includes portable facilities for hemodialysis treatment.

(n) *Center for ambulatory surgery.* – An independent facility of a hospital that provides medical-surgical services to patients that do not require hospitalization.

(o) *Home health services program.* – An institution that offers patients skilled nursing services and other therapeutic services in their homes.

(p) *Health services.* – Any service related to clinical, diagnostic, treatment or rehabilitation aspects, including services related to alcoholism, drug addiction and mental

health, when they are rendered in or through a health facility.

(q) *Pharmacy.* – An establishment registered and authorized by the Secretary of Health in which chemical products, drugs, pharmaceutical products, pharmaceutical or proprietary specialities, prescriptions, medicines and poisons are prepared, preserved, sold and bottled for retail trade, and may also deal with other articles of legal trade, which are customarily sold in drugstores in Puerto Rico.

(r) *Blood bank.* – Any center for collecting, processing and preserving blood obtained from human beings in order to keep it available to be used at any time it may be necessary.

(s) *Clinical laboratory.* – Any institution where bacteriological, microscopical, hematological, serological, biochemical or histopathological examinations are conducted to help in the diagnosis, control, prevention or treatment of diseases of the human race.

(t) *Radiological facilities.* – Facilities dedicated to the diagnosis of diseases through the use of X-ray equipment, sonography, computerized tomography or any other similar equipment for invasive procedures.

(u) *Acquisition.* – To acquire the legal title of land, buildings, medical equipment or property through purchase, option for purchase, lease, or any other form, such as a legacy or donation.

(v) *Capital investment.* – Use of capital for or in favor of a health facility, that according to the generally accepted and consistently applied accounting principles cannot be accounted for as as operating and maintenance expense.

(w) *Highly-specialized medical equipment.* – Medical equipment whose cost exceeds the established minimum investment of two hundred fifty thousand (250,000) dollars or more, and whose acquisition has the purpose of offering a health service.

(x) *Health maintenance organization.* – A public or private organization that meets the requirements of § 1310(d) of the Federal Public Health Act 93-222, as amended, or that:

(1) Provides or offers health services to the participants, including basic health services such as routine medical services, hospitalization, laboratory, radiological, emergency and preventive services, and that also provides these services outside of the service area of the organization.

(2) Offers these services on the basis of the fees paid periodically without taking into consideration the date on which the services are rendered, and that said fee is established regardless of the frequency, use or the type of service that is rendered.

(3) Provides medical services offered mainly by doctors that are employees or partners of the organization or by doctors who are in individual private practice or by doctors in group practice through agreements.

(y) *Affected persons.* – Any person directly affected by the decision of the Secretary regarding a petition for exemption or a certificate of necessity and convenience, including:

(1) The petitioner or applicant.

(2) The health facilities located in the service area of the project, which provide services similar to those proposed.

(3) The health facilities that, prior to receiving the application under consideration, have informed, in writing, their intention to render similar services in the future.

(4) Any agency that establishes rates for the health facilities in Puerto Rico.

(z) *Petitioner or Proponent.* – Any person who plans to carry out any of the activities regulated in §§ 334-334j of this title, whether he be exempted or not of the need to request a certificate of necessity and convenience, pursuant to the provisions of §§ 334-334j of this title. – Nov. 7, 1975, No. 2, p. 922, § 1; July 26, 1979, No. 189, p. 521, § 3; Sept. 19, 1983, No. 16, p. 385, § 3; July 18, 1986, No. 139, p. 441, § 1.

---

§ 334a. Obtaining certificate; activities requiring

No person may acquire or construct a health facility or offer or develop a new health service, or make capital investments for or in favor of a health facility, or acquire highly-specialized medical equipment without having first obtained a certificate of necessity and convenience granted by the Secretary. A certificate of necessity and convenience shall be required for the following activities:

(1) The acquisition of an existing health facility.

(2) The establishment of a new health facility, regardless of the amount of capital investment.

(3) Capital investment made by or in favor of an existing health facility in the amount of five hundred thousand (500,000) dollars or more, including the costs of any study, blueprints, specifications and other activities related to the investment, except in the case of health facilities such as pharmacies, blood banks and clinical laboratories in which a certificate of necessity and convenience will always be required. It will be applicable to the acquisition of facilities through donations, leasing or any other manner if it exceeds the minimum investment established if it had been purchased.

(4) Any increase in the number of beds authorized for a hospital.

(5) Any redistribution of beds between categories even though the authorized capacity is not altered.

(6) Any relocation of beds from one physical facility to another.

(7) The conclusion of a health service which was being offered by or through a facility.

(8) The inclusion of a new health service by, or in favor of a health facility, which has operating expenses of one hundred and fifty thousand (150,000) dollars or more, with the exception of health facilities such as pharmacies, blood banks and clinical laboratories for which a certificate of necessity and convenience will always be required.

(9) The acquisition by any person or health facility of highly-specialized medical equipment valued at two hundred and fifty thousand (250,000) dollars or more which shall be the property of, or located in, a health facility. In the determination of the cost, the cost of studies, blueprints, specifications, taxes and any other activities essential to the acquisition of the equipment will be included.

(10) The acquisition by any ~~person~~ of highly-specialized medical equipment which shall not be property of, nor shall be located in, a health facility, if the equipment is to be used by hospitalized patients. If the equipment is not to be used by hospitalized patients, nor shall it be the property of, nor shall it be located in, a health facility, the acquirer must notify the Secretary, in writing, of his intention of acquiring said equipment and the use it will be given, within a period not greater than thirty (30) days prior to the date on which the acquisition shall be effected. – Nov. 7, 1975, No. 2, p. 922, § 2; July 26, 1979, No. 189, p. 521, § 3; Sept. 19, 1983, No. 16, p. 385, § 4.

---

§ 334a-1. Repealed. Act Sept. 19, 1983, No. 16, p. 385 § 5, eff. Sept. 19, 1983.

---

§ 334b. Criteria for issuing or denying certificate

The Secretary shall establish, through regulations, the criteria to issue or deny the certificate of necessity and convenience. Upon establishing said criteria, the Secretary shall take into consideration the general guidelines established in the federal act and in §§ 334-334j of this title, according to the public policy and development strategy

adopted by the Planning Board, including the Integral Development Plan.

Among said criteria are the following:

(1) The relationship between the transaction for which the certificate is requested, and the long-term service development plan, if any, of the petitioner.

(2) The present and projected need of the population which will be affected by the proposed transaction of the services to be provided thereby.

(3) The existence of alternatives to the transaction for which the certificate is requested, or the possibility of providing the proposed services in a more efficient or less costly manner than that proposed by the petitioner.

(4) The relationship between the health system operating in the area and the proposed transaction.

(5) In the specific case of petitioners for certificates of necessity and convenience to offer health services, the Secretary shall also take into consideration the following factors:

(a) The availability of human and economic resources for the efficient rendering of these services.

(b) The impact that the manner of providing the services shall have on the needs of clinical training of the health professionals of the area in which the services shall be rendered.

(c) The percent of the population of the area to be served which shall have access to the proposed services. The Secretary shall require that the application indicates the time the petitioner will need to make available the

service or equipment for which he is petitioning, or to incur the expenses of the transaction. – Nov. 7, 1975, No. 2, p. 922, added as § 3 on Sept. 19, 1983, No. 16, p. 385, § 5.

---

§ 334c. Exemptions – Regulation

The Secretary shall relieve the health facilities that offer services to hospitalized patients and that comply with the exemption criteria provided by the applicable federal legislation, from the requirement of acquiring the certificate of necessity and convenience.

The Secretary, through regulations, and according to the applicable federal provisions, shall establish the procedural requirements that must be met for the acquisition of an exemption petition filed under this section. – Nov. 7, 1975, No. 2, p. 922, added as § 4 on Sept. 19, 1983, No. 16, p. 385, § 6.

---

§ 334d. Exemptions – Effects of transfer of facility

A health facility or part thereof, or highly-specialized medical equipment, which has been granted an exemption, and a health facility leased by a health maintenance organization that is subsequently sold or leased, cannot continue operating as such, or being used, unless the Secretary issues a certificate of necessity and convenience approving the same, or once again grants the exemption, upon complying with the requirements of § 334c of this title. – Nov. 7, 1975, No. 2, p. 922, added as § 5 on Sept. 19, 1983, No. 16, p. 385, § 7.

---

§ 334e. Repealed. Act Sept. 19, 1983, No. 16, § 7, eff. Sept. 19, 1983.

---

§ 334f. Facilities controlled by another or extensions thereof

If a health maintenance organization or a health facility controlled, directly or indirectly by it, requests a certificate of necessity and convenience, the Secretary shall approve it if the transaction contemplated is indispensable to cover the needs of the present and potential membership thereof, and if the health maintenance organization cannot provide health services through its facilities at a reasonable cost consistent with the organization's long-term operations, and with doctors and health professionals associated with the facility, without carrying out the contemplated transaction. – Nov. 7, 1975, No. 2, p. 922, added as § 6 on Sept. 19, 1983, No. 16, p. 385, § 8.

---

§ 334f-1. Acquisition of organization or equipment already authorized; prerequisite

Any health maintenance organization, any part thereof, or medical equipment which has received a certificate of necessity and convenience under the preceding section cannot be acquired totally or through the acquisition of a majority interest in the same, until it has obtained a new certificate of necessity and convenience authorizing the acquisition. – Nov. 7, 1975, No. 2, p. 922, added as § 6A on Sept. 19, 1983, No. 16, p. 385, § 9.

---

§ 334f-2. Procedure; regulation by Secretary

The Secretary shall establish, through regulations, the procedure for the reception and evaluation of applications for certificates of necessity and convenience or of exemption, in harmony with § 334c of this title, according to the requirements established in §§ 334-334j of this title and in the applicable federal law and regulations. – Nov. 7, 1975, No. 2, p. 922, added as § 7 on Sept. 19, 1983, No. 16, p. 385, § 9.

---

§ 334f-3. Procedure; regulation by Secretary – Notice of transactions

The proponent shall notify the Secretary in writing of his intention of carrying out any of the transactions contemplated by §§ 334-334j of this title, no later than thirty (30) days prior to the date on which he shall file the petition to obtain the certificate of necessity and convenience for said transaction, or request the exemption provided in § 334c of this title. – Nov. 7, 1975, No. 2, p. 922, added as § 8 on Sept. 19, 1983, No. 16, p. 385, § 9.

---

§ 334f-4. Procedure; regulation by Secretary – Petitions for specific purposes

Any petition for a certificate of necessity and convenience required to eliminate imminent safety hazards, or to obtain the reimbursement of expenses for any federal or local program or to meet federal or local requirements regarding operating permits shall be approved after the holding of a hearing, up to the amount needed to meet the listed needs, except when the Secretary determines that the facility or the service for which the investment is to be

made is not necessary. – Nov. 7, 1975, No. 2, p. 922, added as § 8A on Sept. 19, 1983, No. 16, p. 385, § 9.

---

§ 334f-5. Procedure; regulation by Secretary – Petition fees

Any petition to obtain a certificate of necessity and convenience shall be accompanied by an Internal Revenue voucher in the amount of one hundred (100) dollars, with the exception of those filed by the agencies of the Commonwealth of Puerto Rico and its municipalities. The funds thus collected shall be covered into the Health Fund created pursuant to the provisions of §§ 337-337m of this title. – Nov. 7, 1975, No. 2, p. 922, added as § 9 on Sept. 19, 1983, No. 16, p. 385, § 9; July 18, 1986, No. 139, p. 441, § 1.

---

§ 334f-6. Procedure; regulation by Secretary – Notice to affected parties

The Secretary shall inform the affected persons and the general public of the petition through a circular letter, by mail, within thirty (30) days following the receipt thereof. The notice to the general public shall be made through the publication of a summary of the petition in one (1) newspaper of general circulation. – Nov. 7, 1975, No. 2, p. 922, added as § 10 on Sept. 19, 1983, No. 16, p. 385, § 9; July 18, 1986, No. 139, p. 441, § 1.

---

§ 334f-6a. Issuance of permits without consideration of statutory requirements

Notwithstanding any other provision in contravention of §§ 334-334j of this title, or any other laws, the Secretary

of Health shall have the power to issue administratively, without a hearing, those permits, licenses and certificates of necessity and convenience needed for the operation of the health installations to be privatized by virtue of the provisions of §§ 3301-3325 of this title, without taking into consideration the statutory or regulatory requirements relevant to the concession of said permits, licenses and certificates. To such effects, the public deed or contract by which any health facilities are privatized or transferred shall include a clause that provides that concurrently with the signing of the privatization documents, the Secretary shall issue those permits, licenses and certificates of necessity and convenience needed for the immediate operation of said facility. Provided, however, That in case the privatized health installations may wish to subsequently reduce or increase the health services they render, they must meet all the applicable legal provisions, including those of the Certificates of Necessity and Convenience Act. – Nov. 7, 1975, No. 2, added as § 11 on July 6, 1997, No. 31, § 24.

---

§ 334f-7. Issuance of permits without consideration of statutory requirements – Hearing

The Secretary shall be under the obligation of holding an administrative hearing during the evaluation period of the petition, in which the persons affected and those who have requested the opportunity to be heard shall be given the opportunity to participate. Any person who requests to be heard at a hearing shall be entitled to be represented by counsel or any other advisor and to present oral or written arguments or relevant evidence. The Secretary

shall establish by regulations the procedures for holding the hearing.

The Secretary or the official on whom he delegates to preside the hearing shall be empowered to take oaths and to serve summons under pain of contempt, requiring the appearance of witnesses and the production of any relevant or pertinent document or evidence. In the case of refusal to obey a summons or to present the documentary evidence required, the Secretary or his representative may resort to the Court of First Instance to compel the appearance, the statement and the presentation of documents.

The Secretary's findings of fact upheld by evidence shall be conclusive. The complete file of each petition shall be available for inspection by the affected persons during working hours. – Nov. 7, 1975, No. 2, p. 922, added as § 11 on Sept. 19, 1983, No. 16, p. 385, § 9; July 18, 1986, No. 139, p. 441, § 1; renumbered as § 12 on July 6, 1997, No. 31, § 25.

---

§ 334f-7a. Issuance of permits without consideration of statutory requirements – Cases not requiring hearing

No administrative hearings will be held in cases of acquisition, remodeling or expansion of health facilities or health services which are already established and have certificates of necessity and convenience, as long as it does not entail the relocation and the offering or developing of a new health service, or any of the activities contemplated in subsections (4)-(10) of § 334a of this title. – Nov. 7, 1975, No. 2, p. 922, added as § 11-A on July 18, 1986, No. 139,

p. 441, § 2; renumbered as § 12-A on Aug. 8, 1998, No. 206, § 2.

---

§ 334f-8. Issuance of permits without consideration of statutory requirements – Decision and term therefore

The Secretary shall issue the decision on the application to obtain a certificate of necessity and convenience on the basis of the grounds set forth to make such a decision, within the term established in the provisions of §§ 2101 et seq. of Title 3, and in the regulations adopted by the Secretary pursuant to the latter. – Nov. 7, 1975, No. 2, p. 922, added as § 12 on Sept. 19, 1983, No. 16, p. 385, § 9; July 18, 1986, No. 139, p. 441; renumbered as § 13 and amended on Aug. 8, 1998, No. 206, §§ 2, 3.

---

§ 334f-9. Issuance of permits without consideration of statutory requirements – Decision delay; remedy

If the Secretary does not issue a decision on the petition to obtain a certificate of necessity and convenience or on the petition for exemption, during the period of time established in § 334f-8 of this title, the petitioner may resort to the corresponding Part of the Court of First Instance for it to direct the Secretary to issue his decision. – Nov. 7, 1975, No. 2, p. 922, added as § 13 on Sept. 19, 1983, No. 16, p. 385, § 9; renumbered as § 14 on Aug. 8, 1998, No. 206, § 2.

---

§ 334f-10. Issuance of permits without consideration of statutory requirements – Reconsideration and judicial review

Any party adversely affected by a decision of the Secretary to grant, deny, revoke, suspend or modify a certificate of necessity and convenience, may request the reconsideration of the final decision of the Secretary or a judicial review of the same according to and under the terms and conditions provided for such purposes by Reorganization Plan No. 1 of the Judicial Branch, of July 28, 1994, as amended, known as the "Puerto Rico Judicature Act of 1994," and §§ 2101 et seq. of Title 3, known as the "Uniform Administrative Procedures Act of the Commonwealth of Puerto Rico." The Secretary shall render his decision on the request for reconsideration within a term of sixty (60) days counting from the filing thereof. – Nov. 7, 1975, No. 2, p. 922, added as § 14 on Sept. 19, 1983, No. 16, p. 385, § 9; renumbered as § 15 and amended on Aug. 8, 1998, No. 206, §§ 2, 4.

---

§ 334f-11. Repealed. Act Aug. 8, 1998, No. 206, § 1, eff. Aug. 8, 1998.

---

§ 334f-12. Issuance of permits without consideration of statutory requirements – Guarantee of impartiality

Once the case is pending reconsideration or in a subsequent stage, no official who is carrying out functions with regard to the petitions or exemption of certificates of necessity and convenience may establish communication with the petitioner or his representative, or with any person who has opposed the granting of the certificate, nor

his representative, in the absence of the other parties. – Nov. 7, 1975, No. 2, p. 922, added as § 16 on Sept. 19, 1983, No. 16, p. 385, § 9.

---

§ 334f-13. Cancellation or rescission of certificate; grounds

The Secretary may cancel or render ineffective any certificate of necessity and convenience if the person does not carry out the project during the period of time granted, or if he submitted false information in the petition. – Nov. 7, 1975, No. 2, p. 922, added as § 17 on Sept. 19, 1983, No. 16, p. 385, § 9.

---

§ 334f-14. Publicity of petitions

Any person that requests it shall have the right to inspect the evaluated petitions, as well as the other documents used in the consideration thereof. – Nov. 7, 1975, No. 2, p. 922, added as § 18 on Sept. 19, 1983, No. 16, p. 385, § 9.

---

§ 334g. Existing facility; certificate

Any person who is operating highly-specialized medical equipment acquired before this act; and any person who is operating a pharmacy established before October 24, 1979; and any person who is operating a health facility, with the exception of a pharmacy, whose operations began prior to November 7, 1975, shall be entitled to have the Secretary issue a certificate of necessity and convenience without the requirement of the determination of public necessity and convenience and

without the holding of a hearing. – Nov. 7, 1975, No. 2, p. 922, § 8, renumbered as § 7 and amended on July 26, 1979, No. 189, p. 521, § 3; renumbered as § 19 and amended on Sept. 19, 1983, No. 16, p. 385, § 10.

---

§ 334h. Penalties

The violation of the provisions of §§ 334-334j of this title shall constitute a misdemeanor punishable by a fine of not more than five hundred dollars ($500) or a maximum term of imprisonment of six (6) months, or both penalties at the discretion of the court; Provided, That each day in violation of the provisions of §§ 334-334j of this title shall be deemed as a separate offense. The Secretary of the Department of Health is hereby empowered to impose administrative fines after due notice and hearing, for violations of §§ 334- 334j of this title or the regulations or orders issued pursuant to the provisions of §§ 334-334j of this title. Each administrative fine imposed by the Secretary shall not exceed five thousand dollars ($5,000) and shall be paid by certified check issued to the Secretary of the Treasury. The product of said administrative fines shall be covered into the General Fund. – Nov. 7, 1975, No. 2, p. 922, § 9, renumbered as § 8 and amended on July 26, 1979, No. 189, p. 521, § 3; renumbered as § 20 and amended on Sept. 19, 1983, No. 16, p. 385, § 10; Aug. 8, 1998, No. 206, § 5.

---

§ 334i. Injunction

The Secretary of Health may apply for an order of injunction from the Court of First Instance to permanently or temporarily stay any violations of §§ 334- 334j of this

title or of the regulations approved hereunder. – Nov. 7, 1975, No. 2, p. 922, § 10, renumbered as § 9 and amended on July 26, 1979, No. 189, p. 521, § 3; renumbered as § 21 and amended on Sept. 19, 1983, No. 16, p. 385, § 10.

---

§ 334i-1. Pre- and post-election periods

In order to protect the best interests of the parties, no requests for certificates of necessity and convenience may be filed, nor will the Department of Health make any determination on any matter related to these certificates, during pre- and post-election periods.

This prohibition shall include a period of two (2) months before and two (2) months after the general elections are held in Puerto Rico. – Nov. 7, 1975, No. 2, p. 922, added as § 21-A on July 18, 1986, No. 139, p. 441, § 2.

---

§ 334j. Regulations

The Secretary shall promulgate regulations with force of law to establish all matters regarding the applications for certificates of necessity and convenience, and shall establish the standards to insure that the information required from the petitioners shall be that which is necessary and pertinent for the evaluation of the application.

Prior to the approval of the regulations, the Secretary shall hold public hearings, notifying the interested persons by publication in two newspapers of general circulation. The notice shall be published at least fifteen (15) days before the hearing is held. The Secretary shall promulgate the regulations within a period not to exceed six (6) months, counting from the date this act takes effect. – Nov.

7, 1975, No. 2, p. 922, added as § 10 on July 26, 1979, No. 189, p. 521, § 3; renumbered as § 22 and amended on Sept. 19, 1983, No. 16, p. 385, § 10.

COMMONWEALTH OF PUERTO RICO
DEPARTMENT OF HEALTH
SAN JUAN, PUERTO RICO

No. 3335
August 15, 1986

REGULATION OF THE SECRETARY OF HEALTH NO. 56

TO ESTABLISH EVERYTHING RELATED TO THE PETITIONS FOR THE NEED AND CONVENIENCE CERTIFICATE; TO ESTABLISH THE NORMS THAT ARE REQUIRED FROM THE APPLICATNS; TO SET PENALTIES AND FOR OTHER PURPOSES, IN ACCORDANCE TO WHAT IS PROVIDED FOR IN LAW NO. 2 OF NOVEMBER 7, 1975, AS AMENDED; TO REVOKE REGULATION OF THE SECRETARY OF HEALTH NO. 45, APPROVED OCTOBER 1st., 1980.

Article I – LEGAL BASIS

This regulation is promulgated in accordance to Law No. 2 of November 7, 1975, as amended.

Article II – DEFINITIONS

For purposes of this regulation, the following terms shall have the definitions stated as follows:

1. Secretary – Secretary of Health of the Commonwealth of Puerto Rico.
2. Department – Department of Health of the Commonwealth of Puerto Rico.
3. Person – Natural or juridical person.

4. Health Facilities – Hospitals, extended care facilities, health homes, rehabilitation centers, renal disease center, including ambulatory hemodialysis units, ambulatory surgery centers, health in the home service program, diagnosis and treatment center, pharmacies, blood banks, clinical laboratories and radiology facilities, in accordance to how they are defined in the Law.

5. Need and Convenience Certificate – Document issued by the Secretary of Health authorizing one person to carry out any of the activities covered by the Law, certifying that the same is necessary for the population that is to be served and that it will not affect existing services unduly, contributing in that manner to the orderly and adequate development of health services in Puerto Rico.

6. Construction – Construction will include remodeling, expansion, and initiation for the purpose of finishing the construction of the health facility.

7. Hospital – Institution primarily providing to hospitalized patients, by or under medical supervision, diagnosis services, treatments, care or rehabilitation for injured, disabled or sick persons. Includes general hospitals as well as specialized hospitals.

8. Extended Care Facilities (Skilled Nursing Care) – Institution primarily providing skilled nursing care and related health services, to hospitalized patients that, due to their condition, do not require the direct medical supervision provided by a hospital.

9. Diagnosis and Treatment Center – An independent facility or operated in combination with the hospital providing integrated health services for

the diagnosis and treatment of ambulatory patients which makes available by means of arrangements with other health facilities, x-ray and clinical laboratory services.

10. Health Home – An Institution providing health relative care and services to physically and mentally ill persons, who do not require the degree of care and treatment that a hospital or extended care facility provides.

11. Offer or Develop a New Health Service – It shall be considered that a person is proposing to offer or to develop a new health service when he/she proposes to embark in one of the following activities:

    a) The construction, development or establishment of a health facility or in any manner of acquisition.

    b) The addition of a health service by any facility covered by the law which implies operational expenses in excess of the limit established in subsection (8) of Article 2, of the Law.

12. Rehabilitation Center – Institution for hospitalized patients which operates for the purpose of helping in their rehabilitation of physically or mentally disabled persons, through an integrated program of services and others, under the supervision of specialized professional personnel.

13. Renal Dialysis Center – A hospital unit authorized to provide diagnosis, treatment and rehabilitation services to patients with severe renal illnesses. In addition, it includes ambulatory facilities for the treatment of hemodialysis.

14. Ambulatory Surgery Center – Independent facility of a hospital which provides medical-surgical

services to patients which do not require hospitalization.

15. Health Services in the Home Program – Institution which offers patients skilled nursing services and other therapeutical services in the home.

16. Health Service – Any service related to the clinical, diagnosis, treatment or rehabilitation aspects, including services related to alcoholism, drug addiction and mental health, when they are provided as/or through a health facility.

17. Pharmacy – Establishment registered and authorized by the Secretary of Health in which chemical products, drugs, pharmaceutical products, pharmaceutical patented specialties, prescriptions, medicines and poisons are prepared, preserved, sold on a retail basis and packed, in addition being able to deal in other articles of legal commerce which according to the custom are sold in the drug stores of Puerto Rico.

18. Blood Bank – Any center for the collection, processing and preservation of blood obtained form human beings for the purpose of having it available for utilization at any necessary moment.

19. Clinical Laboratory – Any institution in which bacteria logical, microscopy, and hematological, serological, biochemical or histopathological examinations are carried out which help in the diagnosis, control, prevention or treatment of diseases of the human race.

20. Radiological Facilities – A facility dedicated to the diagnosis of illnesses by means of the use of X-ray equipment, Sonogram, Tomograph,

whether computerized or any other type of similar equipment of an invading nature.

21. Acquisition – To acquire the legal title of a plot of land, building, medical equipment or property by means of purchase, purchase option, lease or in any other manner, such as legacy or a donation.

22. Capital Investment – Use of capital by or in favor of a health facility which, in accordance to the generally accepted and consistently applied accounting principals, can not be entered in the ledgers as an operation and maintenance expense.

23. Highly Specialized Medical Equipment – Medical equipment for which the cost exceeds the minimum established investment of two hundred and fifty thousand ($250,000) dollars or more and which acquisition is for the purpose of opening a health service.

24. Health Maintenance Organization – Public or private organization which complies with the requirement of Section 1310 (d) of the Federal Public Health Law 93-222, as amended, or which:

    (a) Provides or offers health services to the participants, including basic health services such as routine medical services, hospitalization services, laboratory, radiology, emergency and preventive services outside of the organization service area.

    (b) Offers these services on the basis of fees paid periodically without taking into consideration the date on which the services are rendered and that said fee is established without considering the frequency, the utilization or the type of service provided.

(c) Provide medical services principally offered by Doctors who are employees or partners of the organization, or by Doctors who have and individual private practice or by Doctors who have group practice by means of equipment.

25. Affected Persons – Any person directly affected by the Secretary's decision in regard to an application for granting a certificate of need or an exemption of a certificate of need, including:

(a) The applicant or propounder

(b) The health facilities located in the service area of the project providing similar services to that proposed.

(c) The health facilities that after the receipt of the application under consideration, have informed their intention of providing similar services in the future in writing.

(d) Any agency which establishes rates for the health facilities in Puerto Rico.

26. Propounder Applicant – That person who is trying to carry out any of the activities regulated in the law, whether they are exempt or not from the need to request a need and convenience certificate in accordance to what is provided for in the law.

27. Remodeling – Improvement or alterations to the facility which alter or modify the authorized health service to be offered or that are geared toward having one of the services contemplated by the Law.

28. Relocation – Relocate a Health facility previously located in specific geographical limit, place a

territory. It does not include the re-ubication of services within the same physical or adjacent structure.

29. Law – Law number 2 of November 7, 1975, as amended.

Article III – APPLICABILITY

This regulation will apply to all persons who plan to carry out any of the following activities:

1. The acquisition of an existing health facility.
2. The establishment of a new health facility, regardless of the capital investment sum.
3. Capital investment made by or in favor of an existing health facility for the amount of five hundred thousand ($500,000) dollars or more, including the costs of any studio, plans, specifications and other activities related to the investment, except when dealing with health facilities that are pharmacies, blood banks, and clinical laboratories, in which a need and convenience certificate will always be required. It applies to the acquisition of facilities by donation, lease or in any other manner if it exceeds the minimum investment established in the event that it is through a purchase.
4. Any increase in the number of beds that are authorized to a hospital.
5. Any redistribution of beds between categories although the authorized capacity is not altered.
6. Any relocation of beds from one physical facility or another.

7. The termination of a health service which has been offered by or through a facility.

8. The inclusion of a new health service by or in favor of a health facility, which implies annual operational expenses of one hundred and fifty thousand ($150,000) dollars or more, except in the health facilities that are drug stores, blood banks and clinical laboratories, in which the need and convenience certificate will always be required.

9. The acquisition by any person or health facility of highly specialized medical equipment with a value of two hundred and fifty thousand ($250,000) dollars or more, which shall be the property of or be located in a health facility. In the determination of the cost, the cost of the study, plans, specifications, excise taxes and that of any other activities which are essential to the acquisition of the equipment shall be included.

10. The acquisition by any person of highly specialized medical equipment that does not belong to, nor is located at a health facility, if the equipment is to be utilized by hospitalized patients. If the equipment will not be utilized by hospitalized patients nor will it be the property of, nor will it be located at a health facility, the acquirer must notify, in writing, the Secretary about his intention to acquire said equipment and the use to which he plans to use it within a period no greater than thirty (30) days before the date when the acquisition is to be formalized.

Article IV – PROCEDURE FOR THE RECEIPT AND EVALUATION OF APPLICATIONS

The procedures adopted to carry out the filing and evaluation of applications for need and convenience certificates shall be the following:

1. Filing of Applications

   a) Before filing an application for a need and convenience certificate, the propounder must notify the Secretary in writing about his intention to carry out the action for which the certificate is being required, no more than thirty (30) days prior to the date when the application is to be filed for the obtainment of a need and convenience certificate or an exemption from the certificate requirement.

   b) The Secretary or his authorized representative, at the request of a party, will offer advice about how to prepare the applications and will indicate, in general terms, the relation of the proposed project with the plans, guidelines and criteria developed in regard to the matter.

   c) All applications must be filed in writing before the Secretary in the forms that the Department provides for that purpose. All applications must be accompanied by an internal revenue voucher for the amount of one hundred (100) dollars, except those filed by the agencies of the Commonwealth of Puerto Rico and its municipalities. The filing of the application will enjoy preference in regard to other similar proposals that are presented later.

2. Notice regarding applications received.

a) Within the term of thirty (30) days counted from the time that the application is filed at the Department of Health, the Secretary of Health or his authorized representative will review the same for the purpose of requiring in writing from the propounder any additional information that may be necessary. The additional information must be sent as soon as possible. After thirty (30) days have passed without receiving said information, the application will be filed.

b) Within thirty (30) days following the receipt of the application, the Secretary or his authorized representative will notify the general public, and the affected persons by means of circular letter. The notification to the general public shall be by means of the publication of the summary of said application in one (1) newspaper of general circulation.

The affected party pursuant to how they are defined in this regulation and the public health facilities that are the closest in the area of the proposed transaction shall be notified by mail. In addition, any person who has requested to be heard will be notified.

c) One it has been determined that the application is complete, the same will be submitted for evaluation by the Department's offices that are responsible for questioning and analyzing everything concerning the need and convenience certificate.

d) The evaluations will include, if necessary, visits and interviews to the facilities in the

area of the proposal and a report regarding the proposal indicating whether the same complies with the general and specific criteria to the facility in question.

e) In those cases in which two or more applications for the same service and/or facility are filed in the same area, if it has been filed within a close period of time, the same shall be evaluated jointly, scheduling to such effect a joing hearing; notifying the propounders about this fact. In those cases in which the propounder has more than two need and convenience certificates issued for similar facilities and services, a new proposal will not be considered until he demonstrates his capacity to adequately take care of the new proposal or proposals.

If there are two or more applications for the same facility or service, with the proposals being basically equal, but one of the applicants has already been issued a need and convenience certificate for that same type of facility or service, once it has been evaluated, the Secretary will give priority to that one for which the propounder does not have a previously issued certificate, as long as he/she complies with the applicable criteria.

f) Any person who so requests it will have the right to inspect the evaluated application, as well as the other documents utilized in the consideration of the same.

g) For the protection of the best interest of the parties no petition shall be filed for a Certificate of need nor the Department shall take any action for certificates of need during the

periods pre and post election. This prohibition shall include the period of two month before and two month after the General Election in Puerto Rico.

Article V – GENERAL GUIDELINES REGARDING EVALUATION OF APPLICATIONS.

1. When evaluating a Need and Convenience Certificate application, the Secretary must consider the following general guidelines:

   a) Relation of the proposed action with the approved State health plan and with the proposed annual plan.

   b) The relation between the transaction for which a certificate is being requested and the long term service development plan, if any, of the applicants.

   c) The existence of alternatives to the transaction for which a certificate is being requested or the possibility of providing the services contemplated in a more efficient or less costly manner from that being proposed by the applicant.

   d) The short and long term financial feasibility, as well as the probable impact of the project on the operational costs and on the charges to the users for the services to be offered by the propounder.

   e) 1. The need had by the percentage of the population that is to be served by the services being proposed and the manner in which the area residents and in particular the low income persons, with physical and mental disabilities, the elderly and other

possible non-privileged groups will have access to those services.

2. In the case of a reduction or elimination of one service, including the relocation of a facility or service, one has to take into consideration:

i) The need had for that service by the population that is currently being served.

ii) The matter in which that need can, in an adequate manner, be covered by the proposed relocation or by alternative arrangements.

iii) The effect that proposed reduction, elimination or relocation could have in regard to persons with low income, physical and mental disabilities, elderly persons and other non-privileged groups to obtain that necessary health service.

f) The contribution of the proposed service being able to fill the health needs of the members of the medically undercared for groups which traditionally have experienced difficulties in obtaining equal access to health services. Particularly those needs which have been identified within the existing health plan, the proposed annual plan and the state health plan.

1) The manner in which the medically undercared for population currently utilizes services similar to the ones being proposed in comparison to the percentage of the population, in the area of the applicants service,

which is medically "under cared for". And the form or reach by which that medically undercared for population is expected to make use of the proposed services.

2) The form or manner in which the applicant has complied with his obligation, if any, under any applicable federal rule requiring service without compensation, community service is accessed to persons who have a physical or mental disability under programs receiving federal assistance.

3) The manner in which the Medicare, Medicaid programs and those of indigent patients in an area are cared for by the applicant.

4) The manner in which the applicant offers a variety of ways or resources by means of which the persons will have access to his/her services.

g) The relation between the health system operating in the area and the proposed transaction.

h) The availability of resources (including personnel in the area of health, managerial personnel and funds for capital and operation needs) to provide the proposed services and the alternative forms of utilizing these resources already identified in the existing health plan, the proposed annual plan or the state health plan.

i) The relation, including the organizational relation, of the proposed service and any subsidiary or referral service.

j) The impact which the manner of providing the health services will have upon the needs of the clinical training programs that the health professionals of the area may have in which the services are to be rendered.

k) If the proposed service is to be available within a limited number of facilities, the manner in which the professional health schools in that area will have access to those services for training purposes.

l) The special needs and circumstances of the entities providing a substantial portion of their services, resources or both, to individuals who do not reside in the service areas where the entities are located or in adjacent areas. These entities must include professional health schools, multidisciplinary clinics and specialized centers.

m) The special needs and circumstances of the health of its impact upon being existing on proposed institutional training programs for Doctors in Osteopathy and Medicine at the levels of students, residents and/or internees.

2. No Need and Convenience Certificate will be issued to applicants who have obtained previously a need and convenience certificate for a similar transaction without having begun to carry out the approved transaction in the proposed area.

3. In addition the Secretary will consider those specific evaluation criteria for the different applications for the Need and Convenience Certificate which make up part of this regulation.

Article VI – SPECIFIC CRITERIA

The Secretary will utilize the specific criteria stated further ahead when evaluating an application for a need and convenience certificate, in addition to the general criteria which appear in Article V of this Regulation.

When an application compares favorable with all the other applicable criteria, after having held a hearing, the application must be approved and the certificate requested will be granted if there is no opposition, in which case it will be adjudicated on its merit. When the same does not fulfill one or more of the applicable criteria, the application can be denied. The propounder must present the information required in his application, and supply the Department with evidence to prove that its criteria applying to his case is being complied with. The greater responsibility of producing the necessary information falls upon the propounder.

For the purpose of the evaluation of applications for need and convenience certificates, the municipality is established as the basic population unit. For those projects, excepting: pharmacies, blood banks, clinical laboratories and conventional radiology facilities, which require a population size greater than that of the municipality, the population of the adjacent municipalities within the same health area, region or sub-region will be considered, such as the latter ones are defined in the corresponding Health Facilities Plan. If the population requirement is of such magnitude that it goes beyond the proceeding criteria, adjacent health areas, regions or sub-regions shall be considered for the purposes of defining the service area.

Due to the fact that the concentration of health physical resources maintain a direct relation to the concentration of human resources, which in turn determine

the level of services which are offered, the municipalities were classified into three (3) categories, to whit:

Category I – Primary Level – This group is made upon by those municipalities where what are mainly offered are primary health services and they do not have secondary level hospitals.

Category II – Secondary Level – Include the municipalities which are the center for health areas or which have secondary care hospitals.

Category III – Tertiary Level – Include the municipalities which are the center of the health regions and sub-regions and where tertiary level services are provided.

The preceeding different categories or levels maintain a relation to the definitions and descriptions presented as follows:

PRIMARY LEVEL:

"It is a practical means of putting indispensable health aid at the reach of all of the individuals and families of the communities, in a manner which is acceptable and proportioned to their resources and with their full participation."[1]

Primary health attention is geared toward the main sanitary problems of the community and provides the corresponding preventive, curative, rehabilitation and

[1] Definition that was drafted at the International Conference on Primary Health care in Alma-Ata, September, 1978, O.M.S.

health promotion services. Their functioning influences the rest of the health system.

This level is of minimum attention with the participation of the community leaders and basic health personnel. Its principal functions: the education of the population in regard to health, immunization, simple preventive and curative actions for pregnant women and healthy children, obstetrical care and transfer of patients to levels with a greater complexity.

It has as its fundamental characteristic to stimulate individual responsibility for one's health and mutual cooperation among members of one's community. Naturally, to assure its success, the education regarding health for the public, the training of certain leaders and the supervision and technical support of the superior level, especially of the basic level of the health system, are indispensable conditions.

The primary aid services are the providing of general sanitary ones offered to the population at the entry point of the health services system.

SECONDARY LEVEL:

This level comprises the providing of specialized services at the instances of the primary aid services. The secondary services generally include: prevention, diagnosis, treatment and rehabilitation services. In addition to the primary level services, it also comprises specialized services in internal medicine, general surgery, pediatrics, obstetrics and gynecology, hospitalization services and auxiliary services such as x-rays and laboratories. The hospitalization services in this level are represented by the area and sub-regional hospitals.

TERTIARY LEVEL:

The tertiary aid comprises very specialized services and even super-specialized services, such as plastic surgery, neurosurgery, neumology and nephrology.

At this level, each region will develop a tertiary hospital to serve as a specialized referral center for the area hospitals. This level will have specialized and subspecialized personnel as well as sophisticated services.

In the evaluation of its application, the service record by the propounder, as well as by the similar providers in the area, will be considered.

The following is the specific criteria established for each type of facility, service or equipment.

SPECIFIC CRITERIA:

1. Hospital – as defined in Art. II(7).

A. Classification:

1. General Hospital –

Specific Criteria:

1. A norm of 2.5 beds of general detailed care for each 1,000 inhabitants will be considered.

2. No hospital will be established already in the area of health services that are operating at 80% annual occupancy.

3. The proposed facility must not be more than 30 minutes away by means of automobile transportation from the primary population to be served.

2. Pediatric Hospital – means an institution of the tertiary level and may provide specialized services for children from newborn to 16 years of age.

   1. Norm of 2.5 beds for each 1,000 children living in the health area to be covered by the services to be offered shall be established.

   2. No pediatric hospitals shall be established, unless the ones established in the proposed health area are operating at 80% annual occupancy.

3. Psychiatric Hospital – means an institution which principally offers institutionalized patients, by or under the supervision of a doctor, diagnostic, treatment services, rehabilitation of mental patients and persons with emotional disturbances.

   1. It will be necessary that the facilities included in the proposed area comply with 80% occupancy.

   2. A norm of .7 beds for each 1,000 inhabitants will be considered.

   3. The fact of whether the facilities close to the proposed area have attended 500 new cases will be taken into account.

4. Tuberculósis Hospital – means an institution which principally provides institutionalized patients, by or under the supervision of a doctor,

with services for the diagnosis and treatment of turberculosis.

1. Services of this nature will be considered when the situation of a specific area or town merit the need for such services.

5. Oncologic Hospital – means an institution for the treatment of degenerative diseases such as cancer, and in which the care is administered by personnel authorized to practice medicine in Puerto Rico.

   1. The construction, development or establishment of facilities of this nature shall be considered in light of the high incidence of the condition in proposed areas.

   2. The availability of existing services in the area shall be an indispensable element to be considered at the moment of determining the need.

6. Extended Care Facilities – (Skilled Nursing Care) To determine the need for additional facilities in the health areas, sub-regions or regions, the following formula shall be utilized.

   1. The ratio of the use of the area (patient days per each 1,000 inhabitants of the population) multiplied by the projected population of the area (in miles) and afterwards divided by 365 to obtain an average daily census.

   2. The average daily census is divided (obtained in the preceding step) by .85 (occupancy factor) and then 10 is added to determine the number of beds needed.

7- Health Home – means an institution, as defined in Article II(10).

1. The need will be determined with the same formula for the extended facilities care.

8- Rehabilitation Center – Health facility for hospitalized patients which operates for the purpose of helping in the rehabilitation of physically or mentally disabled person through an integrated program of medical services and others under the supervision of specialized professional personnel.

9- Renal Dialysis Center – independent unit or in connection with the hospital providing diagnosis, treatment, rehabilitation and hemodialysis services to patients with chronic renal diseases.

1. The need to establish a renal dialysis facility will be considered when the ones established already in the proposed health service area are operating at over 80% of their utilization on an annual basis. An existing facility must be operating two daily shifts, six times a week. Each shift shall have as an average from 5-6 hours for the treatment.

2. All the centers must count with no less than four hemodialysis stations.

3. The proposed facility must not be more than 30 minutes away from the population to be served by means of transportation in an automobile.

4. Any proposed facility which expects to handle at least 20% of its patients in an outpatient manner must carry out 4.0 procedures (treatments) or more per week.

5. A Renal Center for transplants must serve a population of 2 million inhabitants or more. The population basis of its Health Region will be taken into account.

6. A hospital Renal Center must be established in a Region of Health Services in which the population estimate is that of 500,000 inhabitants or more.

7. The need for a facility is bases on the incidence and prevalence rate of patients with permanent renal diseases for the year and the health area where the services are expected to be established.

10. Ambulatory Surgery Centers – means an independent facility or one operated in connection with a hospital providing surgical medial services to patients that do not require hospitalization.

1. The facility must be at least 30 minutes away from a hospital.

2. If a facility is an independent one, they must submit evidence of agreements reached to offer emergency services to patients that need them.

3. A maximum norm of three (3) operating rooms for each ambulatory surgery center will be established.

4. An operating room for ambulatory surgery will be authorized for each 40,000 inhabitants in the proposed health area.

5. An Ambulatory Surgical Center must present evidence of being able to produce a volume of 5 operations per room daily.

6. Any established facility which expects to increase the number of operating rooms must document the application showing that the rooms in use operate 90% of the time, during 12 hours a day for 5 days a week. This norm will be considered when a new facility in the same health service area is planned to be established.

11. Health Services programs in the Home – institution as defined in Article II(15).

    1. The Geographical area to be served by a home health agency must coincide with one (1) of the health areas of the Department of Health.

    2. The ratio of the population per health agency in the home must be that of one agency for each 6,000 elderly.

    3. No additional offices will be considered in the service area until the existing offices in that area have reached or surpassed a total of five hundred (500) patients taken care of during the year.

12. Diagnosis and Treatment Centers – means a facility as defined in Article II(9).

    1. All diagnosis centers established must be at a thirty (30) minutes distance from an existing hospital in the area.

    2. The norm of one CDT per each 50,000 inhabitants in a municipality is established, excluding the government facilities. If it is to be established in a municipality with a population smaller than that of 50,000 inhabitants, not more than on center shall be established.

3. All diagnostic and treatment centers must guarantee the rendering of x-rays, clinical laboratory and pharmacy services to the ambulatory patients.

4. Emergency services will be offered 24 hours a day.

13. Pharmacies – Establishment registered and authorized by the Secretary of Health at which they prepare, preserve, sell and tax surgical product, drugs, pharmaceutical products, pharmaceutical specialties or patented ones, prescriptions, medicine and poisons on a retail basis, in addition, being able to handle other articles of licit commerce which, according to the custom, are sold in the pharmacies of Puerto Rico.

1. A norm of one pharmacy per each 4,000 non-indigent inhabitants is established for all the municipalities, except San Juan, for which the norm shall be that of 3,000 non-indigent inhabitants.

   The ratio of the population per pharmacy shall determine the Category to which the municipality belongs.

   Category I – 9,000 inhabitants per pharmacy

   Category II – 8,000 inhabitants per pharmacy

   Category III – 6,500 inhabitants per pharmacy

   San Juan – 4,000 inhabitants per pharmacy

2. The location will be evaluated on the basis of the need for the service area, which shall be made up on an area located within the radius of one (1) mile from the proposed pharmacy. A service area will be considered to be saturated if it surpasses the applicable population criterion. Provided that, the certificate will not be denied on the basis of the saturation of other service areas for the same municipality. Among the factors that will be considered are the area population density, the floating population, if any, and the access route to reach the proposed facility.

3. The establishment of new pharmacies in an area cannot be authorized until the existing pharmacies at one (1) mile around it have surpassed an average of two thousand (2,000) prescriptions per pharmacy per month, excluding the pharmacies in government institutions. The service schedule and the medical plans accepted by the established pharmacies can be taken into account.

14. Blood Bank – any center for the collection, processing and preservation of blood obtained from human beings for the purpose of having it available to be utilized at any necessary moment.

    1. A blood bank may be established in those municipalities where there is hospital or an ambulatory surgery center.

    2. The applicant must present written evidence of agreements in a hospital or ambulatory surgery center, where it is established

that the blood obtained shall be to satisfy their needs.

3. The processing of the blood obtained must be carried out by a medical technologist, who is licensed by the State.

15. *Clinical Laboratories* – health facilities at which bacteriological, microscopic, hematological, seriological, biochemical or histopathological examinations are carried out which help in the diagnosis, control, preventions or treatment of the human race.

1. The population/clinical laboratory ratio shall be determined by the group which the municipality of the proposed laboratory belongs, in the following manner.

Category I – 14,000 inhabitants per laboratory

Category II – 12,000 inhabitants per laboratory

Category III – 10,000 inhabitants per laboratory

2. The location will be evaluated on the basis of the services area within a radius of one (1) mile from the proposed laboratory. A service area or a municipality shall be considered too saturated if it surpasses the applicable population criterion. Provided that the establishment of a laboratory in a service area will not be denied on the basis of the saturation of other services areas within the same municipality. The population density of the area, the transitory population that it may have, if any, and the

access routes to the proposed facility may be taken into account

3. The establishment of a new clinical laboratory or a bleeding station must not be authorized until the clinical laboratories of the service area will surpass an average of seven thousand (7,000) tests per laboratory on an annual basis.

4. The criteria applied to the clinical laboratories shall apply to the bleeding stations. A certificate of need shall be required for a bleeding station.

16. *Radiology Facilities* – Health facility dedicated to diagnosis of diseases by means of the use of x-ray equipment, sonograph, computerized tomography or any other similar equipment.

1. *Conventional Diagnostic Radiology*

a. The norm of one radiology machine per each twenty thousand (20,000) inhabitants in a municipality is established. The number of x-ray machines that the existing facilities in the proposed area or municipality have will be taken into account.

b. The location will be evaluated on the basis of the service area within the radius of one (1) mile from the proposed facility. A service area or municipality will be considered to be saturated if it surpasses the criterion of twenty thousand (20,000) inhabitants. Provided that the establishment of a radiology facility will not be denied in a service area on the basis of the population of

other service areas of the same municipality. The area population density, the floating population and the access route for reaching the same may be taken into account.

c. No applications will be approved which do not count with the availability of at least one (1) part time radiologist for a minimum of twenty (20) hours a week. Such radiologist must not rule over more than three (3) x-ray facilities, it being understood that the word rule, he/she shall be the professional in charge of the reading in the plates in the facilities.

2. *Computerized Tomographia*

a. The criteria or evaluation norm shall be three hundred thousand (300,000) inhabitants per facility that forms part of the same region of the Department.

b. Only applications for facilities to be located in municipalities which are the head of a Department region shall be approved.

c. No additional equipment of this kind will be authorized until the ones existing in the service area have surpassed at least one thousand (1,000) procedures during one (1) year.

3. *Magnetic Resonance*

a. All applications for a Need and Convenience Certificate to operate magnetic resonance equipments (NMR) must be accompanied by attesting evidence that

the professional in charge of the interpretation and production of the studies of images of the equipment have the following minimum training; training which must have been obtained at duly accredited entities authorized to accredit professional medical studies.

1. Certification from the Examining Board (American Board of Radiology)

2. Three (3) months of training or six (6) months of experience in Nuclear Radiology (nuclear medicine)

3. Six (6) months of training in cross-section anatomy images which must include at least three (3) months of training in Computerized Tomography (CT) or one (1) year of experience with cross-section anatomy images including tomography of the body.

4. Three (3) months of training or six (6) months of experience in neuroradiology.

5. One hundred twenty (120) hours of documented training with magnetic resonance images which includes physics, instrumentation and clinical application.

b. The applicant must include in his application a copy of the contract with the following health professionals, who shall be available at the magnetic resonance unit itself or at an accessible unit to this one, in the following specialties.

(1) Neurology

(2) Neurosurgery

(3) Oncology-Hematology

(4) Cardiology

(5) Pathology

(6) X-ray Technology

(7) Expert Technician in nuclear medicine

c. In addition, he/she must submit a copy of the contract with the medical-hospital facility close to the proposed location to attend any medical emergency which may arise.

d. The application for magnetic resonance (NMR) must include the following modes:

(1) Ultrasound

(2) Computerized Tomography

(3) Nuclear Medicine

(4) Conventional Radiography

e. The application for the need and convenience certificate for an NMR must comply with the following requirements established by the Food and Drug Administration; and the structure where the unit is to be located must comply with the requirements established by the manufacturer and the applicable federal and state requirements.

f. Any application for a need and convenience certificate for a magnetic resonance unit must credit the fact that the

same will be located in the same locale where other radiology machines complementing said service are to be located.

g. The applicant must include evidence of his financial capacity and condition, as stated by a C.P.A.

h. Any application for a need and convenience certificate for a magnetic resonance unit must be accompanied by an environmental impact study.

4. Electronic Microscopy

Population – One for all of Puerto Rico.

Location – Municipality of no less than 20 zones and must be in or affiliated to a medical teaching institution.

5. Linear Accelerator

Population – One for every 1,000,000 inhabitants.

Location – Hospitals that specialize in the treatment of cancer.

6. Lithotripter

a) The propounder of a lithotripter shall submit evidence that for the operation of said equipment has at least the following basic professionals:

1) Urologist – shall be the specialist responsible of the operation of the equipment

2) Anesthesiologist

3) Nurses

4) Radiologist

5) Nefrologist

6) Secretarial staff

7) Technical Staff

The aforementioned professionals, except the clerical personnel, shall be duly qualified by the corresponding examining boards to license such professionals and their specialties.

b. The structure shall have the following facilities:

1. Total radiology, including conventional ascending and descending radiology, sonography and computerized tomography.

2. Patient preparation area.

3. Anesthesia area.

4. Operation room equipped for percutaneous surgery, uteroscopy, citoscopy, enderology for complications during the procedure.

5. Recuperation area.

6. Examination area.

7. Physician offices, clerical offices and nurses facilities.

8. Medical records area.

c) The facility shall have opened faculty for every qualified urologist. The urologist shall have the following qualifications:

1) Certified by the American Board of Urologist.

2) Experience and special courses in the use of the equipment. At least 35 patients in an institution accepted by the authorities from the state or country where such practice is carried out.

2) Privileges in a hospital of the same area.

3) Fulfill the requisites of Act 22 of April 22, 1931, as amended, and with recognized specialty.

d) The propounder shall submit together with his application a financial statement certified by a Certified Public Accountant showing his economic solvency.

e) Submit a viability study for the development of the project.

f) The lithotripter equipments shall be located in a hospital or ambulatory facility, according to Act no. 101 of June 26, 1965, as amended.

g) The equipment shall be approved by the Food and Drug Administration (F.D.A.)

h) Periodical reports shall be submitted to the Secretary of Health as to utilization, services cost, operation and

maintenance cost. Reports of compliance with the established criteria be included.

i) Any proposed agreements with third parties either to the functioning or financing of the equipment shall be previously approved by the Secretary.

j) Shall submit evidence of professional liability insurance.

k) Shall offer services to the medically indigent patients, if his certificate of need is approved.

Article VII – SPECIAL CONSIDERATIONS FOR HEALTH MAINTENANCE ORGANIZATION (HMO'S)

1. The health maintenance organizations (HMO's), like the other health facilities, must apply for and obtain from the Secretary of Health a need and convenience certificate before any of the actions stipulated in Article III of this Regulation.

2. *Exemptions to the Review Requirement*

Some health maintenance organizations and other health facilities which are directly or indirectly controlled by them, will not have to file an application for a need and convenience certificate when they are proposing to carry out any activity included in Article III of this Regulation, as long as that activity is in favor of a health facility principally devoted to offering services to institutionalized patients.

3. To be able to enjoy the aforementioned exemption, they must comply with the following requirements:

a) They must file an exemption application on the date, in the manner and with the information established by the Secretary of Health and they must obtain the approval of the same.

b) The action that they propose to carry out must be in favor of a health facility principally devoted to rendering services to institutionalized patients.

c) It must be one or several of the health maintenance organizations or one or several of the other health facilities detailed further ahead.

d) The payment method for services (pre-paid or rate per service) shall not be relevant when determining whether an exemption is to be granted or not.

4. Requirements in regard to the application for exemption.

a) File an application for exemption in the Department on the date and in the manner required by the Secretary.

b) The application must contain the information regarding the health facility or facilities required by the exemption, including the proposed purchase or lease offer, the manner in which they propose to carry out the acquisition and the financial commitments that they project to engage in.

c) The Secretary approves the application.

d) If on the date of filing of an application for exemption, the proposed health facility or part of the same has not begun to render

services, the Secretary will approve the exemption if he determines that said facility or part of it will fill those exemption requirements that apply to it (which are detailed further ahead) when they begin to render services.

5. Requirements to be fulfilled by the health facility or facilities:

a) It must be a health maintenance organization, pursuant to how it is defined in Law Number 2 of November 7, 1975, as amended, which:

1. It has, within the geographical area to be served, a registration of at least 50,000 persons.

2. The facility where the service is offered or is to be offered is geographically located in such manner that the services are reasonably accessible to the registered persons or members.

3. At least 75% of the patients that are expected to be served are registered (are members) in the organization.

b) It must be a health facility that:

1. Is devoted to or will devote itself to, principally, the care of the institutionalized patients.

2. It is or will be directly or indirectly controlled by a health maintenance organization which has a registration of at least 50,000 persons in the geographical area to be served.

3. It is or will be geographically located in such manner that the service is reasonably accessible to the registration.

4. At least 75% of the patients that are expected to receive the services are registered (are members) in the health maintenance organization.

C. It must be a health facility or a part of the same which:

1. Is or will be leased to a health maintenance organization which has at least 50,000 persons registered in the geographical area to be served.

2. On the date of the filing of the applications for exemption for review, the lease contract has at least fifteen (15) years of legal force.

3. Is or will be geographically located in such manner that the service will be reasonably accessable to the registration.

4. At least 75% of the patients receiving the services will be registered (are members) in the health maintenance organization.

6. Sale, lease, acquisition or use of the health facilities that are exempt from the review requirement.

a) One health facility (or part of the same) to which an exemption for review has been granted may not acquire its control or the control through a lease of the same and the

health facility of the ones described in subsection 5-C cannot be utilized by any other person who is not the tenant, unless he/she complies with the following requirements:

1. The Secretary of Health issues a need and convenience certificate approving the sale, the lease, the acquisition or the use of the same.

2. The Secretary of Health determines, on the basis of an application that is to be filed, that the entity which they propose to sell or rent, which has the intention of acquiring the control or which has the intention of using the facilities, in a health maintenance organization which has, within the geographical area to be served, a registration of least 50,000 persons; and with relation to the health facilities through which the services are to be provided, the same is geographically located in such manner that the services are reasonably accessible to the registered persons or members and at least 75% of the patients who are expected to be served are registered (are members) and the health maintenance organization or it is a health facility that will be principally devoted to the care of institutionalized patients and is or will be directly or indirectly controlled by a health maintenance organization which has a registration of at least 50,000 persons in the geographical area to be served.

7. Inclusion in Health Plans

   a) The Secretary will not deny a need and convenience certificate to a health maintenance organization or a health facility directly or indirectly controlled by a health maintenance organization due to the fact that the proposal is not included in the State Health Plan or in the annual implementation plan.

8. Mandatory Approval

   a) The Secretary will approve an application for a need and convenience certificate from a health maintenance organization or from a health facility directly or indirectly controlled by a health maintenance organization, if he determines that:

      1) The approval of said application is indispensable to be able to cover the needs of the registration or new members which can reasonable be expected to be recruited by said organization.

      2) The health maintenance organization cannot provide, through services or facilities that could be available, if health services are the reasonable cost which would be consistent with the usual functioning of an HMO, for long periods of time through Doctors and other health professionals associated with it.

9. Sale, acquisition or lease of facilities included in this Article, which have been issued a need and convenience certificate.

   a) A health facility (or part of it) of the ones mentioned in this Article to which a need and convenience certificate has been issued

cannot be sold or leased, nor can its control or control in the lease of the same be acquired unless the Secretary issues a need and convenience certificate approving the sale, acquisition or lease of the same.

Article VIII – PROCEDURES FOR THE ADMINISTRATIVE HEARING

In accordance with Article II of the Law, the following procedure shall be mandatory in the administrative hearing:

1. The propounder, the affected parties and any other person who expresses an interest in appearing shall be notified by mail. Said notice shall be sent at least fifteen (15) days prior to the date of the celebration of the hearing.

2. No applications for suspension of hearings will be considered, except when extraordinary circumstances are involved, and if they are presented in writing at least five (5) days prior to the scheduled date. If the motive for the application for suspension is that the propounder or his/her attorney have a previous engagement for the same date, the application must be accompanied with the copy of said scheduled engagement. If the suspension is granted, the party which requested it is obligated to immediately inform the other parties that were to have appeared, as well as the affected persons.

3. In those cases in which after prior citation, the propounder does not appear at the hearing, an unextendible term of fifteen (15) days shall be granted in which to demonstrate the reasons why the application should not be filed. The file that

is ordered in such manner shall be without prejudice of filing a new petition.

4. Only those persons that would have stated their intention to offer evidence during the hearing within fifteen (15) days after having been notified by mail about the presentation of the application or the publication of the edicts, whichever occurred later, can be the only ones to offer evidence.

5. Once the hearing has been held, no briefs about new documentary evidence or new proof can be accepted except those that were agreed upon during the hearing.

6. The Secretary or the Examining Officer assigned to preside over the hearing will have a faculty to take oaths and issue citations under warning of contempt requiring the appearance of witnesses and the production of any document or evidence that is relevant or pertinent.

   If they refuse to appear of produce the documents requested, the Secretary may to the Superior Court to force the appearance, declaration and/or presentation of documents.

7. When one of the parties is interested in the citation of the witnesses, they must submit the names and correct postal addresses of the same in writing, with no less than ten (10) calendar days prior to the public audience. The subpoenas of witnesses shall be done by mail, by telephone or by telex.

8. The hearing will be held before an Examining Officer who will receive the evidence presented, if any, and submit a report to the Secretary recommending the action to be taken including

determinations of facts and conclusions of law in the same.

9. The hearings will be recorded and the compliance with the due process of law shall be watched our for. After fifteen (15) days have elapsed after the Secretary's Decision has been rendered firmly, the recordings may be erased.

10. During the hearing, the parties participating in the same will have the right to cross-examine.

11. No party, including the affected persons, can communicate with and examining officer who will be presiding over the hearing, once it has been scheduled.

12. If the propounder were not to appear at the scheduled hearing after having been validly subpoenaed, the Department will proceed with the hearing if there are interested persons who wish to express themselves about the matter and if there are none, paragraph 3 of this article shall apply.

13. The propounder will begin with a presentation of all the evidence or information relevant to the proposal. Once he has finished his exposition, the other interested persons may endorse or oppose the proposal. Afterwards, the propounder will have an opportunity to rebut or clarify what has been stated by the other persons who expressed themselves in favor of or against the proposal.

14. Any person who participated in the hearing may record, at his own cost, the proceeding held during the same.

15. No administrative hearings shall be held in those cases of acquisition, remodeling or expansion of health facilities or of health services already

established and with of certificate of need if they do not carry the relocation and the offering or development of a new health service or any of the activities named in paragraph 4 to 10 of Article II of the Law.

16. An administrative hearing shall not be necessary in the following situation:

    a) When a new ubication is going to be less 400 meters of the facility in operation.

    b) When is a change of owner and the Secretary of Health finds out that the health interest are duly protected.

    c) Expansion of the facility that do not exceed the quantities established in the Law.

Article – IX TERM OF LEGAL FORCE OF THE NEED AND CONVENIENCE CERTIFICATE

1. Any Need and Convenience Certificate will be left without effect if the product were not developed within the term of one year from the date of its issuance on, or within the extension term granted by the Secretary.

2. This original legal force term shall be considered to be a final one, except when the same has been extended by the Secretary up to a maximum of three years from the date of the issuance of the certificate onwards, by means of a timely petition from the interest party as long as they present evidence demonstrating reasonable progress in the development in the authorized action.

3. In the cases in which issued certificate involves a construction project for which the cost is more than five hundred thousand (500,000) dollars, no additional extensions will be granted unless the

construction has been begun within the one year following the date of the issuance.

4. The decision to grant the extension will be based on what is provided for in this regulation, on the pressing needs for the proposed health services on the date of its petition, and on the expenses and efforts incurred in by the applicant on the date of his application for extension.

5. Any application for extension of legal force must be filed sixty (60) days before the date of the expiration of the certificate. If not filed within that period no action shall be taken.

6. None of the aforementioned shall be an obstacle to have the need certificate revoked due to the petitioner not having adjusted himself to the work schedule indicated in the approved application for the need certificate. Such revocation shall not be carried out without first offering the petitioner a reasonable opportunity to justify his tardiness.

7. The need and convenience certificate shall be non-transferable.

8. The need and convenience certificate can be revoked at any moment if it is shown that the petitioner knowingly submitted information that he knew was false. Any person who has had a need and convenience certificate revoked can request an administrative hearing within the term of 30 days after having been notified about the revocation of the certificate.

9. That person who has been granted a need and convenience certificate and who allows the legal force of the same to expire, is prevented from presenting a new application to have another

need certificate granted to them for the operation of a similar facility or health service for the term of one year counted from the date of its issuance onwards.

Article X – DECISION OF THE SECRETARY

1. The Secretary will issue his decision granting or denying the need and convenience certificate on the basis of the recommendation made to him by the examining officer and on the information appearing in the record in regard to the application in question. In the event of his decision being contrary to the recommendation made by the examining officer who presided over the hearing, the Secretary must state in his decision the reasons why he did not follow the recommendations.

2. The Secretary will issue the decision regarding the application to obtain a need and convenience certificate within the term of ninety (90) days counted form the last date of notice of the application together with the reasons for his decision the general public.

3. The Secretary's findings of facts, supported by evidence, shall be concluding ones.

4. The Secretary will notify the propounder and the affected parties about his decision by certified mail with return receipt requested.

Article XI – RECONSIDERATION

1. Any person adversely affected by a determination of the Secretary, including the propounder, can request a reconsideration of the same in writing within the thirty (30) days following the receipt of his notice. Any person who is interposing a petition for reconsideration will be obligated to

notify at the same time as his interposition a copy of his petition for reconsideration to the persons who appeared at the original hearing or have formulated comments to the original petition in writing, before said hearing. The nonfulfillment of this requirement will deprive the Secretary from jurisdiction to deal with the petition for reconsideration.

2. The Secretary must issue his decision regarding the petition for reconsideration within the term of sixty (60) days form the filing of the same, except in cases in which said petition, at the request of the petitioner, is scheduled for hearing, in which cases the Secretary must issue his decision within the thirty (30) days following the termination of such hearing.

3. A petition for reconsideration can, at the discretion of the Secretary, be scheduled for hearing only if the petitioner were to present a just cause for it. For the purpose of determining the existence of just cause, the following criteria will be taken into consideration:

   a) That the petitioner submit information or additional date relevant to the petition presented, which were not able to be obtained by the petitioner for the hearing in spite of the diligence demonstrated by him/her.

   b) That the petitioner show that significant changes in the factors or circumstances opened which the Secretary based his determination have taken place.

   c) That the petitioner show that the Secretary violated the procedures established by law

or by regulation in regard to the process for the evaluation of an application.

d) Any other grounds which the Secretary determines does constitute just cause.

4. At the reconsideration hearing, only those persons who appeared at the original hearing or who, prior to said hearing, formulated their comments regarding the petition in question in writing, will be able to intervene. The norms established in this Regulation in regard to the petition for suspension, recording of the proceedings and procedures to be followed during the same shall be of application to the reconsideration hearing.

5. The Secretary must notify the petitioner and the corresponding affected parties about whether or not he is scheduling for hearing an application for reconsideration within the term of twenty (20) days, in which case the same must be held within the thirty (30) days following said scheduling notice.

6. Any effected person who wishes to oppose themselves to a petition for reconsideration must do so within the ten (10) days following his/her being notified about the same; otherwise, he/her opposition shall not be considered.

Article XII – JUDICIAL REVIEW

Any person on adversely affected by a determination from the Secretary granting of denying a need and convenience certificate or an exemption of said certificate, including the petitioner, can revert to the corresponding Room of the Superior Court in judicial review within the thirty (30) days following the notice in writing regarding the decision

granting of denying the need and convenience certificate, the exemption or the reconsideration.

Article XIII – EFFECTIVENESS OF THE NEED AND CONVENIENCE CERTIFICATE

Once a need and convenience certificate has been issued, the same shall not become effective until the passing of the term in which to request a reconsideration of the Secretary's decision or to request a judicial review of it without its having been done so or, in the contrary case, until the same has been resolved in a final manner. Notwithstanding, the Secretary may decree that a need an convenience certificate is immediately effective, but in such case, must state the reasons on which such a decision is based.

Article XIV – INJUNCTION PETITION

The Secretary may request from the Superior Court an Injunction Order to prohibit in a provisional or permanent manner any violation to the Law or to the regulations approved by virtue of the same.

Article XV – PENALTIES

Te Secretary of Health may impose administrative fines up to a maximum of five hundred (500) dollars, after prior notice and hearing, for violations to the aforementioned Law, to its regulation and orders issued in accordance o their provisions.

Article XVI – TERMS USED

In word used in singular shall be understood to also include the plural when its use so justifies it; in like manner, the masculine will also include the feminine.

Article XVII – REPEAL CLAUSE

Any other norm or part of the same, promulgated by the Secretary, up to the point where it is incompatible with the provisions of these is by means of the present (document) repealed; as well as Regulation of the Secretary of Health No. 45, approved on October 1st, 1980.

Article XVIII – PROTECTED CLAUSE

Any person who is operating highly specialized medical equipment acquired prior to the law; and any person who is operating a pharmacy established from before October 24, 1979; when any person who is operating a health facility, except a pharmacy, whose operation began prior to November 7, 1975, will have the right to have the Secretary issue him a need and convenience certificate without the determination for the public need or convenience requirement and without the celebration of a hearing.

Article XIX – SEPARATION OF CLAUSES

In any part of this Regulation were to be declared null or unconstitutional, such nullity will not affect the rest of the same.

Article XX – AMENDMENTS

For the purpose of complying with the legislative intention consigned in the Law, it is provided that present regulation cannot be amended without a prior celebration of public hearing, which shall be notified by means of publication in two newspapers of general circulation at least fifteen (15) days before that celebration.

Article XXI – EFFECTIVE DATE

This Regulation shall be effective thirty (30) days after being filed at the office of the Secretary of State in accordance to what is provided for in Law regarding Regulations, of 1958.

CERTIFIED TRANSLATION

COMMONWEALTH OF PUERTO RICO
DEPARTMENT OF HEALTH

HEALTH SECRETARY REGULATION No. 112 TO GOVERN THE ASSESSING PROCESS OF APPLICATIONS FOR GRANTING CERTIFICATES OF NEED AND CONVENIENCE

INDEX

HEALTH SECRETARY REGULATION No. 112 TO GOVERN THE ASSESSING PROCESS OF APPLICATIONS FOR GRANTING CERTIFICATES OF NEED AND CONVENIENCE

Article I – LEGAL GROUNDS

This regulation is enacted pursuant to the provisions of Act No. 2 of November 7, 1975, as amended and Act No. 170 of August 12, 1988, as amended.

Article II – PURPOSE

The purpose of enacting this regulation is to respond to the need of accommodating the changes suffered by the health system, under the light of the public policy as to the rendering of health services in the Commonwealth of Puerto Rico, as defined in the provisions of Acts No. 190 of September 5, 1996 and No. 2 of November 7, 1975, as amended, as well as to update the regulation so that it would include all those technological findings in health services that may be available to the Puerto Rican population.

Article III – DEFINITIONS

For the purpose of this Regulation, the following terms shall have the meaning indicated below:

1. Proposed Action – Means the rendering of a health service, the acquisition, construction, expansion, remodeling or re-location of a health facility, the investment of capital made for or on behalf of a health facility, the increase, decrease or reclassification of beds in a health facility, the termination of a health service and the acquisition of highly

specialized medical equipment and any other action that according to the provisions hereof would require the prior issuance of a Certificate of Need and Convenience.

2. Acquisition – To acquire in excess of 50% of proprietary participation on a legal title of a plot of land, building, medical equipment or property, through purchase, lease, or any other manner, such as bequest or donation. Does not include the purchase of stocks or social participations.

3. Service Area – Means that geographical area in which the proponent is projecting to substantially perform the proposed action, and as provided in article V, paragraph 2(c) of this Regulation.

4. Blood Bank – Any center to collect, process and preserve blood obtained from human beings, in order to have it available to be used at any time that it becomes necessary.

5. Health Facility – Institution as defined in Section 331a (6) of Title 24 of LPRA, for profit or not providing room and care and services related to health to two (2) or more physically or mentally ill, that do not require the degree and treatment of a hospital.

6. Outpatient Surgery Center – Facilities independent from hospital providing surgical-medical services to patients who do not require hospitalization, including facilities with lipotractors unit and cardiac catheterism.

7. Diagnosis and Treatment Center – An independent facility or one operated in combination with a hospital that provides integrated

health services, for the diagnosis and treatment of outpatients, with an emergency ward: and that renders or makes it available, through arrangements with other health facilities, conventional radiology, pharmacy and clinical laboratories services.

8. Renal Dialyses Center – A unit within a hospital, authorized to provide diagnosis, treatment and rehabilitation services to patients with chronic renal ailments, to wit: permanent renal damage; it further includes outpatient facilities to provide treatment with the different dialyses modalities.

9. Rehabilitation Center – Institution for in-house patients that operates with the purpose of assisting in the rehabilitation of physically or mentally disabled persons, through an integrated program of medical services and others, under the supervision of specialized professional staff.

10. Certificate of Need and Convenience – Document issued by the Secretary of Health authorizing a person to perform any of the activities covered by this Regulation and Act No. 2 of November 7, 1975, and that certifies that said activity is necessary for the population that it would serve; shall not contribute to increase the costs of this type of service and shall not improperly affect the services already existing in the area to be served, so that it shall contribute to the orderly and proper development of health services in Puerto Rico.

11. Construction – Shall include from the beginning of a construction, up to any remodeling or enlargement subsequent of the premises that is performed in order to finish or improve the building with a health facility in it.

12. Department – Department of Health of the Commonwealth of Puerto Rico.

13. Highly Specialized Medical Equipment – Medical equipment whose acquisition cost, as defined by Act No. 2, supra, shall exceed the established minimum investment of $250,000.00, which acquisition be in order to offer a health service and that shall be located in an existing authorized health facility in accordance to the Act, supra.

14. Extension of Effectiveness – Shall be that extension or additional term that the Secretary of Health authorized to the original effectiveness granted in a Certificate of Need and Convenience.

15. Extended Care Facilities – Institution that mainly provides skilled nursing care and related health services to in-house patients, who by their conditions do not require the direct medical supervision provided by a hospital.

16. Health Facilities – Hospitals, extended care facilities, health centers, home health programs, hospices, rehabilitation centers, renal ailments centers, including outpatient units and hemo-dialyses, outpatient surgery and its modalities centers, diagnosis and treatment centers, and radiological facilities as described in Act No. 2, supra, and herein.

17. Health Facilities of the same type – that health facility that renders health services within the same classification or definition herein, because it has a Certificate of Need and Convenience authorizing it to do so; to render such services and that also renders the services to the same type of patient (outpatient versus in-house or hospitalized).

18. Radiological Facilities – Health facility devoted to the diagnosis of ailments, through the use of X Rays equipment, sonography, computerized tomography, Positrons Emissions Tomography (PET), lineal accelerators, or any other similar equipment including mammography, magnetic resonance, bone densimetry, angiography, nuclear medicine and any modality of diagnosis or radiological therapy.

19. Pharmacy – Establishment authorized by the Secretary of Health, in which chemical products, drugs, pharmaceutical products, pharmaceutical specialties, prescriptions, medicines and poisons be prepared, preserved, sold and packaged at the retail level, where you could, also, traffic in some other legal articles, which according to tradition be sold in the Puerto Rican pharmacies.

20. Hospice – Institution offering palliative care services to patients in a terminal stage, when life expectancy be of six months or less, if their conditions would follow their normal course, and as defined in Act No. 187 of August 24, 2000.

21. Hospital – Institution that would mainly provide services to hospitalized patients, by

or under medical supervision; these services include diagnosis, treatment, care or rehabilitation of injured, disabled or ailing persons. It includes general hospitals as well as specialized hospitals.

22. Specialized Hospital – Institution that would mainly provide services to hospitalized patients, by or under medical supervision, for the diagnosis, treatment, care or rehabilitation of injured, disabled or ailing persons, in which 80% of its occupation, based on days/patients and beds in use, offers services in Pediatrics, Psychiatry, Oncological or any other additional specialty that the Secretary of Health may determine, pursuant to the development of medicine in Puerto Rico.

23. Tertiary Hospital – Institution that provides health services in two or more of the following specialties: cardiovascular surgery, neonatal intensive care units and pediatrics, neurosurgery, organ transplants, as well as other sub-specialized services through the use of sophisticated technology equipment and facilities.

24. Capital Investment – Use of capital by or on behalf of a health facility that according to generally accepted and consistently applied accounting principles, cannot be accounted as an operation and maintenance expense. It includes the remodeling, construction and acquisition, as defined herein.

25. Clinical Laboratory – Any institution where bacteriological, microscopical, hematological, serological, biochemical or histopathology

tests are performed to help in the diagnosis, control, prevention or treatment of ailments in human beings, including electronic microscopy.

26. To offer or develop a new health service – It shall be considered that a person in proposing to offer or develop a new health service when it proposes to start one of the following activities:

    a. The building, development or establishment of a health facility or any form of acquisition of a health facility.

    b. To add a health service to any facility covered by Act No. 2, supra, that would entail operational expenses in excess of the limit set in paragraph (8) of Article 2 of said Act and article VIII hereof, when said limit is applicable.

    c. To add or offer a health service that is not being rendered by or at the health facility adding the same, in the prior twelve (12) months.

27. Organization for maintenance of health – Public or private organization that complies with the requirements of Section 1310(d) of the Federal Public Health Act 93-222, as amended or that:

    a. It provides or offers health services to participants, including basic services of health, such as routine medical services, hospitalization services, laboratory, radiology, emergency and preventive services, and that, also, covers those

services outside the service area of the organization.

b. It offers those services based on quotas paid periodically without taking into consideration the date on which the services are rendered and that said quota is set without considering the frequency, sue or type of service rendered.

c. It provides medical services mainly through physicians who are employees or partners in the organization, or by physicians practicing privately individually, or by physicians who practice in groups, through agreements.

28. Affected Person – Any person directly affected by the decision of the Secretary Certificate regarding an extension application or an authorization for a Certificate Need and Convenience, including:

a. Applicant or promoter.

b. The health facilities of the same type, as defined in the provisions hereof, having a CNC issued or those being located and operating in the applicable service area and that provides services of the same type, as defined herein.

c. The health facilities that, prior to receive the application under consideration, have reported in writing their intention to render services of the same type in immediate future, or that has already presented an application at S.A.R.A.F.S.

d. Any agency setting rates to the health facilities in Puerto Rico.

29. Person – Any person natural or juridical.

30. Floating Population – It shall be that population not residing within a particular geographical zone and that would visit or transfer to such geographical zone due to its job, study or any other habitual or consequent activity. In the case of a facility in which the service area be a radial mile, the estimate to be used for floating population shall be that which can be obtained from available and pertinent information coming from the closest place to the place where the proposed facility shall be located. The methodology used shall have to exclude the resident population.

31. Resident Population – Shall be that population centralized and estimated by the Federal Bureau of the Census, the Planning Board or any other governmental state or federal organism, having its permanent residence within a geographical zone.

32. At Home Health Services Program – Organization that offers skill nursing service and other therapeutic services to at home patients.

33. Region – For the purposes of this Regulation it shall only mean the following geographical zones that are listed below, comprised in turn of several sub-regions and municipalities:

    a. Metropolitan Region; includes the following sub-regions and the corresponding municipalities for each sub-region.

i. San Juan Sub-region: San Juan and Guaynabo

ii. Carolina Sub-region: Carolina, Canóvanas, Loíza and Trujillo Alto.

iii. Fajardo Sub-region: Fajardo, Río Grande, Luquillo, Ceiba, Culebra and Vieques.

b. Northern Region: includes the following areas and the corresponding municipalities for each area.

i. Arecibo Sub-region: Arecibo, Camuy, Hatillo, Lares, Quebradilla and Utuado.

ii. Manatí Sub-region: Manatí, Barceloneta, Ciales, Florida, Morovis, Vega Baja.

c. Northeastern Region: Includes the following areas and the corresponding municipalities for each area.

i. Bayamón Sub-region: Bayamón, Toa Alta and Vega Alta.

ii. Cataño Sub-region: Cataño, Dorado and Toa Baja.

iii. Barranquitas Sub-region: Barranquitas, Comerio, Corozal, Naranjito and Orocovis.

d. Eastern Region: Includes the following areas and the corresponding municipalities for each area.

i. Caguas Sub-region: Caguas, Aguas Buenas, Gurabo, Juncos and San Lorenzo

ii. Cayey Sub-region: Cayey, Aibonito and Cidra

iii. Humacao Sub-region: Humacao, Las Piedras, Maunabo, Naguabo and Yabucoa.

e. Western Region: Includes the following areas and the corresponding municipalities for each area

i. Mayaguez Sub-region: Mayaguez, Añasco, Cabo Rojo, Hormigueros, Las Marías, Maricao and Rincón.

ii. San Germán Sub-region: San Germán, Lajas and Sabana Grande.

iii. Aguadilla Sub-region: Aguadilla, Aguada, Isabela, Moca and San Sebastián.

f. Southern Region: Includes the following areas and the corresponding municipalities for each area

i. Ponce Sub-region: Ponce, Adjuntas, Coamo, Jayuya, Juana Díaz, Santa Isabel and Villalba

ii. Guayama Sub-region: Guayama, Arroyo, Patillas and Salinas.

iii. Yauco Sub-region: Yauco, Guánica, Guayanilla and Peñuelas.

34. Relocate – Relocate a health facility previously authorized and that is operating at a certain geographical limit or place, to a different one, but within the same geographical

zone for which it was originally authorized. Does not include the relocation within the same physical premises or contiguous thereto.

35. Remodeling – Improvements or alterations to a health facility that would modify the health service previously authorized or that it would go addressed to add a service from those contemplated by law and this Regulation.

36. Secretary – Secretary of Health of the Commonwealth of Puerto Rico.

37. Health Service – Any service related to clinical aspects of diagnosis, treatment or rehabilitation, including services related to treatment for alcoholism, drugs addiction and mental health, when they are rendered in or through a health facility.

38. Applicant or proponent – That person projecting the rendering of any of the activities regulated by sections 334a, 334j of title 24 LPRA, exempt or not from requesting a Certificate of Need and Convenience, pursuant to the provisions of sections 334a, 334j of said title.

39. Sub-region – Those geographical delimitations comprising a health region.

40. Mobile Unit – An extension of a previously authorized facility to operate in a specific area, rendering its services through a unit which capacity to be transferred, allows it to offer its services at different locations, but always within the area for which it was authorized in the convenience and need certificate as base facility.

Article IV – APPLICABILITY

1. The provisions of this Regulation shall be applicable to any person who directly or through any agent or proxy, is planning to render any of the activities described below.

a. The acquisition of an existing health facility.

b. The establishment of a new health facility, regardless of the amount of capital investment.

c. The capital investment made for or on behalf of an existing health facility, in the amount of $500,000.00 or more, including the cost of any study, plans, specifications and other activities related to the investment, except that when it is about health facilities that are pharmacies, blood banks and clinical laboratories, for which a Convenience and Need Certificate shall always be required. It applies to the acquisition of facilities by donation, lease or any other manner of purchase.

d. Any increase in the number of beds authorized to a hospital.

e. Any redistribution of beds among categories, even though the authorized amount is not altered.

f. Any relocation of beds from a physical facility to another.

g. The termination of a health service that has been offered by or through the health facility.

h. To add a new health service for or on behalf of a health facility, entailing operational costs of $150,000.00 or more, except the

health facilities that are pharmacies, blood banks and clinical laboratories, which shall always require a Convenience and Need Certificate.

i. The acquisition by any person or health facility of highly specialized health medical equipment with a value of $250,000.00 or more, which shall be owned or shall be located at a health facility. In the determination of the cost, the cost for studies, plans, specifications, excise taxes and any other essential activities for the acquisition of the equipment shall be included.

j. It would not be necessary to obtain a Convenience and Need Certificate for a mere replacement of highly specialized equipment, as long as the replacement equipment would perform substantially the same function or procedure than the equipment to be replaced.

k. The acquisition by any person of highly specialized medical equipment that would not belong to, nor would it be located within a health facility, if the equipment would be used by hospitalized patients. If the equipment is not to be used by hospitalized persons, nor shall it belong to or be placed within a health facility, the purchaser must notify in writing, to the Secretary its intention of acquiring such equipment and the use that it would have, within a term of no more than thirty (30) days before the date in which the purchase is to be formalize.

2. Any person eligible to take advantage of an extension of the convenience and need certificate, as it comes forth provisions c, h, I and j of paragraph 1, shall present at the Assistant Secretary's Office for the Regulation and Accreditation of Health Facilities (S.A.R.A.F.S. for its Spanish language acronym) a request for extension with the following document, as applicable.

a. Evidence showing that the capital investment shall not go over the stipulated amount; the operational expenses related to the new health service, itemized and quantified, indicating whey they would not exceed those established. The mere allegation of a written communication shall not be ready. The estimate of the capital investment or the estimated operational costs, as the case may be, shall be certified by a certified public accountant.

b. An original and recent quotation for the medical equipment to be purchased including the excise taxes and the amount of any cost related to the purchase, such as transportation, delivery and installation. The estimate of related costs must be certified by a certified public accountant.

c. In the case of the purchase of equipment for the substitution of one in use, a sworn statement by the owner, representative or authorized officer of the health facility shall be included, whereby it is certified that this equipment shall be used to substitute the existing one. The application shall include the make and model of the equipment in use and the equipment to be purchased, as well as the reasons for the substitution.

3. If the total cost of the different prior exceptions does not go over the amount established, S.A.R.A.F.S. shall certify that it is not necessary to obtain a convenience and need certificate.

Article V – PROCEDURE FOR THE RECEIPT AND ASSESSMENT OF APPLICATIONS

1. Any proponent must notify the Secretary in writing, as to its intention of performing any activity or transaction that would require the concession of a convenience and need certificate, or the issuance of a exception certificate, with no less than 30 days in advance from the date in which its application is to be presented for the granting of the Convenience and Need Certificate, or the exception certificate, through a letter of intention.

2. Any application must be presented in writing, using the form determined by the Department of Health for that purpose, original and copy, at S.A.R.A.F.S. and must come accompanied by the following documents:

a. A voucher from Internal Revenue in the amount of $100.00, except those applications filed by any instrumentality of the Commonwealth of Puerto Rico, the U.S. Government or any Municipal Government, which shall be exempt.

b. A certificate indicating the name, mailing and physical addresses of all those health facilities of the same type existing in the corresponding service area, according to the type of health facility to be established. In the event of those health facilities whose service area be a radial mile, in addition, it must include with the application, a zoning

map certified by a licensed surveyor or civil engineer indicating the mile radius and the health facilities located in the corresponding mile.

c. Evidence that the premise or proposed premise has a zoning that would allow the establishment of the health service requested; if the premises are not owned by applicant, it shall be accompanied by a lease commitment, in writing, from the owner of the same. In the event of being a project to be constructed as of obtaining the convenience and need certificate, evidence shall be included of the steps taken to certify that the project may obtain the necessary permits for its construction, from the pertinent agencies.

d. Evidence that applicant may recruit specialized technical personnel with the necessary professional capacity to operate the requested health facility, including the possible sources from where the staff to be hired shall come.

e. An economic feasibility study of the project, which shall include an analysis of the functional and operational viability of the proposed action, under the light of: the provisions hereof, as well as the impact of the same, if any, in relation to the existing health facilities in the service area of the proposed action. The study shall include, also, a financial analysis, with a description of the methodology used, a description of the service area including the offer and demand of the area to be served and the socio-economic impact of the proposal. The study

shall include an analysis on the capacity that the existing facilities may have to attend the existing demand of services to be offered. The viability study of the project shall performed its analysis in consideration of the applicable service area in accordance to the health facility requested.

i. For the analysis of specialized hospitals applications, home health services programs, including hospices and radiological facilities, such as: radiotherapy center, positrons emission tomography (PET), electronic microscopy and extra-corporeal lithotripter, the health Region shall be considered as the relevant service area.

ii. For the analysis of applications for the establishment of general hospitals, blood banks, histopathology laboratories, extended care facilities, hospital and outpatient dialysis, magnetic resonance, rehabilitation center, outpatient renal dialysis center, outpatient surgery center, health home, computerized tomography, angiography and nuclear medicine the Sub-region shall be considered as the basic service area.

iii. For the establishment of any diagnostic and treatment center, the municipality shall be considered as the basic service area.

iv. For the analysis of the applications for the establishment of pharmacies, clinical laboratories and conventional radiology facilities, with services such as: X Rays, bone densitometry, sonograms and mammography, an area equivalent to one radial mile, measured from the center of the

proposed structure, shall be considered as the basic service area.

f. The time that applicant estimate it shall need to perform the proposed action.

3. S.A.R.A.F.S. could not act on any application if the same is missing of any of the preceding requirements. S.A.R.A.F.S. could grant a maximum term of 15 days to proponent to complete the application, after which, the same shall be dismissed without prejudice.

4. Within a maximum of 30 days, counted from the date of the presentation of the application, or when the same is completed by proponent, S.A.R.A.F.S. may proceed to publish one notice, once, on a general circulation newspaper in the island, with a summary of the proposed action and likewise it shall notify the persons affected by the proposed action, who are within the service area where the facility would be established, through a circular letter.

5. The notification to the affected persons shall advise as to the right to file, before the Administrative Hearing Division of the Legal Affairs Office of the Health Department, its opposition to the granting of the Convenience and Need Certificate requested, within the peremptory term of 15 days, from the date of the sending of the notices mentioned above according to the post office canceling stamp, or the date of publication of the edict, which ever is later. If an affected party, as per the definition herein, wishes to exercise its right to oppose the application of the Convenience and Need Certificate, it shall have to so notify within the term indicated above, by sending a notice to S.A.R.A.F.S., and a copy of the same, by certified mail, to the proponent of the application. The party exercising its right to oppose shall be liable for reviewing and examining

the record of the application, of which it may obtain a copy, after paying the corresponding fee.

6. S.A.R.A.F.S. shall prepare a report including the names and addresses of the persons affected, located within the applicable service area, who were notified by mail as to the proposed action, which shall be included in the applicant's record. Further, before sending the record to the Administrative Hearings Division, it shall send copy of the report to the proponent.

7. Proponent shall be liable for reviewing the report sent by S.A.R.A.F.S. and to notify any affected person that has not been notified or included by S.A.R.A.F.S. This notice shall be done by mail with return receipt requested and evidence of said notice shall be submitted for the record of the proposal.

8. In all cases of radiological facilities applications, as defined herein, notice of the proposed action shall be sent to the Radiological Health Division of the Health Department, which shall have the right to take part in the process, if so deemed convenient.

9. Once all the notices have been performed, the publication of the edict and the notice of the record to proponent, S.A.R.A.F.S. shall sent forthwith the record to the Administrative Hearings Division of the Legal Affairs Officers, for the scheduling of the public hearing, in those cases so warranting it.

10. After fifteen (15) days have elapsed, as provided by Law and this Regulation, for an affected party to notify its intention of taking part in the process, the Administrative Hearings Division shall certify the proponent, the names and addresses of those persons who have timely sent the

written communication stating their interest in taking part. From then on, proponent must notify such persons with copies of any document it present at the Administrative Hearings Division.

11. The administrative procedure and the holding of the public hearing shall be governed by the provisions of the Uniform Administrative Procedures Act and the Regulation of the Secretary of Health to Regulate the Adjudicative Procedures of the Department of Health and its Dependencies. Party proponent shall have during the entire administrative procedure, the weight of the evidence and the obligation to establish that its application satisfies the applicable general and specific criteria.

12. The holding of an administrative hearing shall not be required, neither the notifications provided in Article 10 of Act No. 2 of November 7, 1975 and in this Regulation, except the publication of an edict, whenever an existing health facility or an authorized health service and in operation, be relocated within the same service area for which it was authorized. This provision shall not apply to the facilities whose area of service according hereto, be a health region or a sub-region. Nothing of the above shall hinder the holding of an investigative hearing or the requirement of papers, documents and information from applicant, when as per the judgment by the Secretary the same becomes necessary and convenient for the proper assessment of the application of a Convenience and Need Certificate in these circumstances; or whenever an opposition to the application, in which case, the administrative hearing shall be held.

13. Those applications that by provision of law does not require the holding of an adjudicative hearing, shall be

referred to the Secretary of Health directly by the Legal Affairs Office.

14. Those applications of Convenience and Need Certificates for health facilities of the same type, that have been presented at S.A.R.A.F.S. within a term of three (3) months one from the other, shall be consolidated to be assessed in a joint administrative hearing, as long as the course of the subsequent assessment process of the same has not been put off in such a manner that the consolidation of the same would produce a delay in the steps and harm to one of the parties. This shall not hinder the fact that it could be consolidated with other applications, if it is shown that the consolidation is convenient for the assessment of the same and the fundamental purpose to achieve an orderly planning of health facilities.

Article VI – GUIDELINES ON THE ASSESSMENT OF APPLICATIONS

In the process of assessing the applications for the granting of a Convenience and Need Certificate, the Secretary of Health shall take into account, to the degree that it would apply to the case, the following elements or general assessment criteria; provided that in the mentioned assessing process the Secretary shall maintain the necessary discretion to weigh and examine said criteria, in such manner and form that would facilitate to enforce the provisions of Act No. 2 of November 7, 1975, as amended and the public policy of the Department of Health.

Further, the Secretary of Health shall have the discretion to harmonize, modify or stay the approval of convenience and need certificates, as necessary, to guarantee the

health of the population and the better access to the health services.

The general elements or criteria are:

1. The relation between the transaction for which the certificate is requested and the development plan for long term services, if any, by applicant.

2. The present and projected need the population to be affected by the transaction contemplated of the services to be provided through the same may have.

3. The existence of alternatives to the transaction for which the certificate is requested or the possibility of providing the services contemplated in a more efficient manner, or a less costly than the one proposed by applicant.

4. The relationship between the operating health system in the area and the proposed transaction.

5. In the specific case of applicants of Convenience and Need Certificates for the offering of health services, the Secretary must also consider the following elements:

    i. The availability of human and economic resources for the efficient rendering of those services.

    ii. The impact that the manner of providing the services would have over the clinical training needs that may have the health professionals of the area where the services shall be rendered.

iii. The percentage of the population of the area to be served that shall have access to the proposed services.

iv. The Secretary shall demand that the application indicates the time the applicant shall need to make the service or equipment object of the request available, or to perform the expense object of the transaction.

6. The existence of a demand for the services to be rendered, going over that amount which would be sufficient to allow the feasibility of the health facility proposed.

Article VII – PARTICULAR CRITERIA BY HEALTH FACILITY

The Secretary shall use particular criteria for each health facility that are listed further down, when assessing an application for convenience and need certificate, in addition to the general guidelines appearing on Article VI, hereof. Whenever an application compare favorably with all applicable criteria, before holding a hearing and not have any grounded opposition, the request may be approved and the requested certificate shall be granted. When the same does not fulfill one or more applicable criteria, the application could be denied.

Proponent must present the information required in the application and shall have the weight to provide the necessary evidence to prove that it fulfils the general and particular criteria applicable to its case. The main responsibility of producing the necessary information in order to be able to assess an application shall fall over proponent.

PARTICULAR CRITERIA:

A. Hospitals – Institution as defined by Article III, Paragraph 21.

The floating population shall be the only one taken into consideration in hospitals cases offering tertiary or specialized services.

To approve any increase in the beds capacity of any hospital, it must be shown that the same does not entail an excess in the offer for the service area.

Whenever a general hospital requests specialized beds, it shall comply with the relationship beds/patients, provided by specialized hospitals.

General Hospital – The Sub-region is hereby established as service area for this facility.

1- A general rule of 2.5 beds of acute care for each 1,000 inhabitants is hereby established as general rule for the establishment of new hospitals. Only those acute beds that are in use shall be taken into consideration, unless that at the time of the assessment of the application, any of the hospitals in the service area would show that, in a term of nor more than six (6) months, it shall be using those beds for which it has a certification in effect, issued by the Secretary.

2- The establishment of a hospital shall not be authorized unless those established in the service area be operating at 80% of average occupation, in the last 12 consecutives months. For the occupation average, only the acute care beds in general hospital being used shall be taken into account.

3- Applicant shall include documentary evidence that it has the capacity to recruit nursing staff to attend to the needs of the population it is proposing to serve.

4- To approve any increase in the capacity of beds of an existing facility, it must be shown that the same does not entails an excess in the offer for the service area.

Specialized Hospital – Institution that is defined in Article III, Paragraph 22. The Region is established as the service area for this type of facility.

A rule of 2 beds per each 1,000 inhabitants in the applicable health area, excepting the psychiatry hospital, is herein established.

Neonatal Care Unit (NICU) – Specialized unit within a tertiary hospital, that renders services of newly born intensive care.

1- Proponent must project the number of total live birth and determine the rate of children with weight under 1,500 grams to establish the coefficient of low weight for the health Region. The coefficient shall be multiplied times 0.0045 (NICU beds need coefficient).

2- The coefficient shall be multiplied times the number of live births projected for the service area to obtain the number of neonatal care beds (NICU).

3- The unit to be established must have a minimum of 15 beds.

4- Applicant shall include documentary evidence that it has the capacity to recruit

specialized nursing staff to attend the needs it proposes to serve.

5- To approve any increase in the capacity of an existing unit, it must be shown that the same would not entail an excess of offer for the service area.

Pediatric Hospital – Institution in which 80% of its operation comes from children, from newly born up to 18 years old, and in which general and specialized services are rendered.

1. A general rule of 2 beds per each 1,000 children is hereby established. Only the pediatric beds being used shall be taken into account, unless that at the time of assessing the application, some of the service area hospitals would show that, in a term of no more than six (6) months, it shall have those beds for which it has an effective certification, issued by the Secretary, in use.

2. No additional pediatric hospital may be established, unless the ones established in the proposed health area be operating at a 70% of occupation, in the last period of 12 consecutive months.

3- Applicant shall include documentary evidence to show it has the capacity to recruit the specialized nursing staff to attend to the needs of the population that it proposes to serve.

4- To approve any increase in the capacity of an existing facility, it must be shown that the same would not entail an excess of offer for the service area.

Psychiatry Hospital – It means a facility for hospitalized patients offering services by or under the supervision of a physician, of diagnosis, treatment and rehabilitation of mental patients and persons with emotional distress.

1. A rule of .5 beds per each 1,000 inhabitants of the health area is hereby established.

2. Only the psychiatry beds being used shall be taken into account, unless that at the time of assessing the application, some of the service area hospitals would show that, in a term of no more than six (6) months, it shall have those beds for which it has an effective certification, issued by the Secretary, in use.

3. No additional psychiatry hospital may be established unless those established in the proposed service area reach a 75% of occupation in the last period of 12 consecutive months.

4. Applicant shall include documentary evidence to show it has the capacity to recruit the specialized nursing staff to attend to the needs of the population that it proposes to serve.

5. To approve any increase in the capacity of an existing facility, it must be shown that the same would not entail an excess of offer for the service area.

B. Extended Care Facility – (skilled nursing care) Institution as defined in Articlle III, Paragraph 15. The Sub-region is hereby established as the basic service area.

The rate of use of these services shall be established in consideration of the population of each of the following age groups: 0-64; 65-74; 75-84 and 85 or over.

1- The rate of days/patients shall be considered for the population (of each age group) per each 1,000 and then shall be divided into 365 to obtain a daily average census. It shall be applied to the projections of the population by age group for the year in which it is contemplated to start the facility's operation.

2- The different values of the age groups shall be added and this result shall be divided by 365 and a daily patients census shall be obtained for the service area.

3- No additional facility of extended care shall be established, unless those established in the proposed service area reach a 75% of occupation in the last period of 12 consecutive months.

4- In order to approve any increase in the capacity of an existing facility, it must be shown that the same does not entail an excess of the offer for the service area.

C. Home Health – Means an institution, as defined in Article III, Paragraph 5.

The Sub-region is hereby established as the service area for these facilities. The need shall be determined with the same formula as the one for extended care facilities.

D. Rehabilitation Center – Means an institution as defined in Article III, Paragraph 9.

The Sub-region is hereby established as the service area for these facilities.

1. A general rule of 4 rehabilitation beds per each 1,000 inhabitants is hereby established.

2. Applicant shall include documentary evidence that it has the capacity to recruit multidisciplinary staff to attend to the needs of the population it proposes to serve.

3. It shall show that it can render or make available other health services that could be necessary for in-house patients.

4. It shall document that it has the capacity to offer emergency services to patients in crisis, or to have an agreement with an institution providing the service within the health Sub-region where it shall render the services.

E. Renal Dialysis Center – Shall mean an institution as defined in Article iii, Paragraph 8. The Sub-region is hereby established as the service area for these facilities.

1. The need to establish a renal dialysis facility shall be considered when those established in the proposed health service area be operating three (3) shifts with an 80% of use on a yearly basis.

2. The existing facilities must be operating a minimum of two daily shifts, six times a week. Each shift shall have an average of 3-4 hours per treatment.

3. Every center shall have at least 15 hemodialysis stations.

4. The proposed facility shall be 15 minutes away from a hospital facility and shall show that it has a support contract with a hospital within that distance in time.

5. The need for a facility shall be based on the incidence and prevalence rate of patients with permanent renal ailments for the pertinent year and in the health area where the service shall be established. This need shall be validated by the Renal Council of Puerto Rico or any other recognized entity with statistics as to the incidence of renal ailments in Puerto Rico.

6. To approve any increase in the number of authorized stations of an existing facility, it must be shown that the same does not entail an excess in the offer for the service area.

F. Outpatient Surgery Centers – It means an institution as defined in Article III, Paragraph 6. The Sub-region is hereby established as the service area, except for facilities with lithotripter units, for which it shall be the Region and the laboratories for cardiac catherism, for which the health Sub-region is hereby established.

1. A rate of 120 outpatient surgeries per each 1000 inhabitants is hereby established.

2. The rate shall be applied to the projection of population for the year in which the start of the operation of the facility is being contemplated. This result shall be multiplied times 1.5 hours (average time for this type of procedure and its recovery). The result shall be divided by 1,164 (80% of the capacity in hours of a surgery room) to obtain the demand for surgery rooms in the service area.

3. Upon considering the service area facilities, the hospital operating rooms devoted an 80% to outpatient procedures shall be included.

4. A minimum of three (3) outpatient surgery rooms shall be required by facility.

5. The facility shall submit evidence of an agreement with a hospital to offer emergency service to patients who may need it and shall be 30 minutes away from that hospital with which it has this agreement.

6. Any established facility contemplating the increase of operating rooms, shall show with its application that the authorized operating rooms operate 95% of time, during 10 hours a day, 5 days a week.

7. To approve any increase in the capacity of an existing facility, it must be shown that the same does not entail an excess of the offer for the service area.

Extra-corporeal lithotripter – An outpatient surgery modality in which a lithotripter that issues chock waves guided by fluoroscopy for therapeutic purposes is used.

The Region is hereby established as the basic service area for this type of facility. The floating population could be taken into account when estimating the population to be served.

1. Proponent shall provide documentary evidence that it shall have the following basic personnel in order to operate the equipment: urologist (a professional in the handling of the equipment); anesthesiologist; nurses, consulting radiologist; consulting

nephrologists; 1 specialized technical and duly certified staff member.

2. The structure where the extra-corporeal lithotripter shall be located must have the following facilities:

   a. Conventional radiology and sonogram facilities.

   b. Patient preparation and pre-anesthesia area.

   c. Operations room, equipped with facilities to perform a percutaneous uretoscopy, cystoscopy and enduology to attend any complication that may arise as a consequence of the treatment.

   d. Recovery area.

   e. Patient examination area.

   f. Ambulances own by the facility or to show that it has a contract for ambulance service.

3. The facility where the extra-corporeal lithotripter must have an open faculty to every qualified urologist.

4. The lithotripter equipment shall be preferably located in a hospital facility, but it cold be established in an outpatient service facility authorized under Act No. 101 of June 26, 1965, as amended.

5. Whenever the unit be at an outpatient facility, it shall be within a distance of not more that 30 minutes from a hospital and shall have a support agreement with that hospital institution.

6. Proponent must bind itself to, if authorized, render services to patients receiving the Health Reform.

Cardiac Catheterism Laboratory

The Sub-region is hereby established as the basic service area for this type of facility.

1. A rate of 4.5 procedures for each 1,000 inhabitants is hereby established.
2. The rate shall be applied to the population projection for the year in which the starting of the operation is contemplated.
3. The facility must provide evidence of agreements with a hospital to offer emergency services to patients who may need it and the same must be 15 minutes away from that hospital with which it has the agreement.
4. It could be considered favorably if the facility would be established in a hospital.

G. Home Health Services Programs – Institution as defined in Article III, Paragraph 32.

Home Health Program

A rule of one (1) program of health services per each 100,000 inhabitants, for each health Region, is hereby established. No additional programs shall be considered in the service area until the existing ones have gone over 500 patients during the preceding year.

Hospice – Service that can be rendered at home or to hospitalized patients, that are at the final stage, as

established by Medicare. The Region is hereby established as the service area for this facility.

1. A rule of one (1) hospice program per each 100,000 inhabitants is hereby established per each health Region.

2. The entrance of an additional hospice program shall not be allowed, until the programs in the Region had attended to an yearly average of 250 patients.

3. If the hospice is to render services as part of a hospital institution, it shall comply with the specialized hospital criteria, as to the relationship beds/patients.

H. Diagnosis and Treatment Centers – It means a facility as defined in Article III, Paragraph 7. The municipality is hereby established as the service area for this facility.

1. Any diagnosis and treatment center shall be 30 minutes away from a hospital.

2. A rule is hereby established of a DTC per each 25,000 inhabitants in a municipality. If the application is to establish a facility in a municipality with a population below 25,000 inhabitants, not more than one could be established in that municipality.

3. Any diagnostic and treatment center must guarantee the rendering of the conventional radiology, clinical laboratory and pharmacy in its facilities or through contracts with external providers.

4. Any diagnostic and treatment center shall offer the service of an emergency ward.

5. In those municipalities not having a hospital, the service of an emergency ward must be offered 24 hours a day.

6. Proponent must bind itself to, if authorized, render services to patients with the Health Reform card.

I. Pharmacies – It means a facility as defined in Article III, paragraph 19.

A rule is hereby established that a pharmacy per each 4,000 inhabitants for all municipalities, except San Juan, Bayamón, Arecibo, Manatí, Ponce, Mayaguez and Humacao, for which the rule shall be 2,500 inhabitants.

The Secretary of Health may add additional municipalities to this exception list, after a determination that those municipalities reached characteristics in the health services offered that would justify their inclusion, such as the amount of hospitals in the municipality and the relation of physicians per population.

The location shall be assessed based on the need of the area located within a one (1) mile radius of the proposed pharmacy. The service area shall be considered as saturated, if it goes over the applicable resident population criteria.

Among the elements that could be considered are: the population density of the area, the floating population, as defined in Article III, paragraph 30, if any, and the access roads to reach the proposed facility. Provided that the certificate shall not be denied due to the saturation of other areas within the same municipality.

1. The establishment of new pharmacies could not be authorized within a service area,

until it is shown that the demand, within the radial mile, goes over the offer in that amount sufficient to allow the feasibility of the proposed pharmacy.

2. Proponent must show, to the satisfaction of the Secretary, that it can hire the necessary pharmaceutical staff to cover the proposed service schedule.

3. When assessing the application, how the service schedule, the amount of inventory of ethical medications and the medical plans that proponent shall offer, compare with those of the established pharmacies, could be taken into account.

4. To approve any increase in the amount of facilities existing in a mile, it shall shown that the same would not entail an excess of the demand for the service area.

J. Blood Bank – A center to collect, process and preserve blood obtained from human beings, in order to have it available to be used at any time when it becomes necessary.

1. Blood banks could be established in those municipalities where there is at least one hospital or outpatient surgery center.

2. Applicant has to present written evidence of the agreements with a hospital or outpatient surgery center, where it would be established that the blood obtained shall be to cover their needs.

3. The procedure of obtaining blood has to be performed by a medical technologist,

licensed by the Commonwealth of Puerto Rico.

K. Clinical Laboratories – It means a facility as defined in Article III, paragraph 25.

A rule of one clinical laboratory per each 5,000 inhabitants is hereby established for all municipalities, except San Juan, Bayamón, Arecibo, Manatí, Ponce, Mayaguez and Humacao, for which the rule shall be 3,000 inhabitants.

The Secretary of Health could add additional municipalities to this exception list, after a determination that these municipalities reached characteristics in the health services offered, that would justify their inclusion, such as the amount of hospitals in the municipality and the physicians/population relationship.

The location shall be assessed based on the need of the area located within the radius of one (1) mile from the proposed laboratory, except in the cases of histopathology laboratories for which the service area shall be the Subregion.

1. The service area shall be considered as saturated if it goes over the applicable resident population criteria. Among the elements that could be considered are: the population density of the area, the floating population, as defined in Article III, paragraph 30, if any, and the access roads to reach the proposed facility. Provided that the certificate shall not be denied due to the saturation of other areas within the same municipality.

2. Proponent must show, to the satisfaction of the Secretary, that it can hire the necessary

pharmaceutical staff to cover the proposed service schedule.

3. When assessing the application, how the service schedule, the amount of inventory of ethical medications and the medical plans that proponent shall offer, compare with those of the established pharmacies, could be taken into account.

4. The establishment of additional clinical laboratories in a service area could not be authorized, until it is shown that the demand, within the radial mile, would go over the offer in that amount sufficient to allow the feasibility of the proposed laboratory.

Histopathology Laboratory

A rule of one histopathology laboratory per each 100,000 inhabitant for the health Sub-region is hereby established.

Electric Microscopy

The Region is hereby established as the basic service area for this type of facility. The facility must be affiliated to a medical teaching institution.

L. Radiological Facilities – It means a facility as defined in Article III, paragraph 18. Different service areas are established, depending on the type of radiological facility that would be established.

Conventional Diagnostic Radiology

A rule of one conventional diagnostic radiology laboratory per each 5,000 inhabitants for all municipalities, except

San Juan, Bayamón, Arecibo, Manatí, Ponce, Mayaguez and Humacao, for which the rule shall be 3,000 inhabitants, as hereby established. The Secretary of Health may add additional municipalities to this exception list, after a determination that these municipalities reached characteristics in the health services offered, that would justify their inclusion, such as the amount of hospital in the municipality and the physicians/population relationship.

1. The location shall be assessed based on the service area need, which shall be comprised by the area located within the radius of one (1) mile from the conventional diagnostic radiology laboratory. The service area shall be considered as saturated if it goes over the applicable resident population criteria. Provided that the certificate shall not be denied due to the saturation of other areas within the same municipality. Among the elements that could be considered are: the population density of the area, the floating population, as defined in Article III, paragraph 30, if any, and the access roads to reach the proposed facility.

2. No applications lacking the availability of at least one (1) radiologist on a part time basis for a minimum of twenty (20) hours per week shall be approve. The in house radiologist could not be in charge of the reading of X Rays in more than three (3) conventional diagnostic radiology facilities.

3. Proponent shall show to the satisfaction of the Secretary that it could hire the necessary technical staff to cover the proposed service schedule.

4. The comparison of the service schedule, the technical sophistication of the equipment and the medical plans offered by proponent with other established facilities, could be taken into account when assessing the application.

5. The establishment of new conventional diagnosis radiology laboratories could not be authorized within a service area, until it is shown that the demand, within the radial mile, goes over the offer in that amount sufficient to allow the feasibility of the proposed facility.

Computerized Tomography

A rule of a computerized tomography facility per each 25,000 inhabitants for the health Sub-region is hereby established.

1. No additional equipment of this type shall be authorized untii the existing facilities in the service area had gone over a thousand (1,000) procedures in one (1) year.

2. The fact that the equipment would be installed at a hospital would be taken as an element to be favorably considered.

3. Proponent must show, to the satisfaction of the Secretary, that it can hire the necessary technical staff to offer the proposed service. Any professional in charge of the interpretation shall have a minimum training in this modality, provided by institutions duly credited by the Accreditation Council for Graduate Medical Education (ACGME) and

certified by the American Board of Radiology.

4. The establishment of new computerized tomography facilities could not be authorized within a service area, until it is shown that the demand, within the service area mile, goes over the offer in that amount sufficient to allow the feasibility of the proposed new facility.

5. The Secretary of Health may consider favorably an application that would propose to share the computerized tomography equipment, with a PET or radiotherapy facility.

Magnetic Resonance

A rule of one magnetic resonance facility per each 50,000 inhabitants per health Sub-region is hereby established.

1. No additional equipment of this type shall be authorized until the existing facilities in the service area had gone over one thousand (1,000) procedures in one (1) year.

2. The fact that the equipment would be installed in a hospital shall be taken as an element to be favorably considered.

3. Any application for a Convenience and Need Certificate for a magnetic resonance facility must be accompanied by clear evidence that the professional in charge of the interpretation and production of the images studies has a minimum training in this modality from institutions duly credited by the Accreditation Council for Graduate Medical

Education (ACGME) and certified by the American Board of Radiology.

4. The establishment of new magnetic resonance facilities could not be authorized within a service area, until it is shown that the demand, within the radial mile, goes over the offer in that amount sufficient to allow the feasibility of the proposed facility.

Nuclear Medicine – Medical specialty that uses nuclear properties of the radioactive nuclides as a technique to produce images to diagnose, handle, treat and prevent ailments, through the use of radio-medication.

The Sub-region is hereby established as the basic service area for this type of facility. A rule of one facility per 50,000 inhabitants for the health Sub-region is hereby established.

Every convenience and need certificate application for a nuclear medicine facility must be accompanied by clear evidence that the professional in charge of the interpretation, production or use of nuclear medicine has a minimum two years training in a nuclear medicine program at an institution credited by the Accreditation Council for Graduate Medical Education (ACGME).

Likewise the form shall include documentary evidence that the technical staff that shall work at the facility has the training and certifications from accredited institutions that would guarantee the necessary knowledge and skills in the procedure and handling of radiation.

Radiotherapy Center

The Region is hereby established as the basic service area for this type of facility. A rule of one facility per each 150,000 inhabitants is hereby established per health Region, with the exception of those regions having an oncological hospital, in which additional facilities could be authorized.

1. Every radiotherapy must have one (1) additional lineal accelerator as back-up support.

2. Proponent must bind itself, it authorized, to render services to Health Reform recipients.

3. An additional facility may be authorized if it is shown that those existing receive 500 patients or more per year.

4. Every radiotherapy center shall be located at a distance in time of not more than 30 minutes from a hospital facility with which is must have an agreement of support.

Positrons Emission Tomography (PET) - A method that produces three-dimensional high intensity images rebuilt by computer, which measure and determine the function or physiology o a particular organ, a tumor o any other metabolic activity.

The Region is established as the basic service area for this type of facility. No facility of this type could be approved until there is a cyclotron available in Puerto Rico. The floating population could be taken into account in assessing the population to be served.

1. A rule of one PET per each 400,000 inhabitants, up to a maximum of two (2) PETs per Region is hereby established.

2. The professional in charge of the interpretation of these studies shall have evidence of having received training at a PET modality during its residency in diagnostic radiology or in lieu thereof, having received a number of continued medical education in this modality at credited institutions.

3. The authorized facility shall render periodic reports to the Secretary of Health as to the use, cost per service, operation costs and maintenance costs.

4. Proponent must bind itself to, if authorized, render services to patients of the Health Reform.

5. The Secretary of Health may favorably consider an application that would propose sharing the PET equipment with a radiotherapy or nuclear medicine facility.

Article VIII – SPECIAL APPLICATIONS AND EXEMPTIONS

1- Every health maintenance organization (HMO) shall request and obtain a Convenience and Need Certificate to perform any of the activities described in Article III hereof, except that such activities be on behalf of a health facility mainly devoted to offer services to institutionalized patients.

2- Whenever a health maintenance organization (HMO) or health facility directly or indirectly control by it, requests a Convenience and Need Certificate the same shall be approved, if the contemplated transaction is indispensable to cover the needs of the potential present enrollment of the organization and the same cannot provide the

health services for long periods of time and with physicians associated with the facility, at a cost that would be reasonable and consequent with the manner of operation of the organization.

3- In the event of those health maintenance organizations (HMO) whose operation has been approved by the Secretary of Health and Welfare of the U.S.A. Government, under the applicable federal legislation, who wants to offer services in Puerto Rico, the Secretary may issue to them, at its request, a Convenience and Need Certificate that would authorize it to perform its activities, to the degree in which the same are developed in accordance to the applicable federal legislation and regulation.

4- Every exemption application should be addressed to the Secretary, accompanied by an explanatory memorandum including the evidence of its accreditation by the Department of Health and Welfare of the U.S. Government and a description of the health services to be provided, the way in which said services would be provided and the number of beneficiaries enrolled in the health facility.

5- In the case the proposed action would entail inherent risks to safety or to achieve reimbursement or the receipt of expenses of funds coming from some program sponsored by the U.S. Government or by the Puerto Rican Government, or to comply with local or federal requirements related to operation permits, the application shall be approved by the Secretary, after holding a public hearing, up to the necessary amount to satisfy the needs listed, except when the Secretary, in the exercise of his discretion, would conclude that the facility or service proposed is not necessary or convenient.

6- A health facility to which a Convenience and Need Certificate has been issued could not be sold or lease, nor could it sell its control of over 50%, or the control of the lease thereof, unless the Secretary would issue a Convenience and Need Certificate approving the sale, acquisition or lease of the same.

Article IX – TERM AND EFFECTIVENESS OF THE CONVENIENCE AND NEED CERTIFICATE

1- Any Convenience and Need Certificate issued by the Secretary shall have a term of effectiveness equivalent to the time estimated by proponent that it would take to perform the proposed action, or one (1) year from its issuance, as the case may be, provided that the Secretary is hereby empowered to limit or to extend said term, depending on the particular circumstances.

2- Through a request of extension of the term duly documented and grounded, and presented before S.A.R.A.F.S. 30 days before the Certificate, the Secretary may, upon its discretion, extend the term of effectiveness of the Certificate for that period of time deemed reasonable to perform the proposed action. Any request for extension of the effectiveness must come accompanied by the documents necessary to justify the reasons for which the action has not been performed in the time the proponent estimated in its application, as well as the documents necessary for the Secretary to assess the reasonability of the extension term requested.

3- The Convenience and Need Certificate shall not be transferable.

4- The convenience and need certificate may be voided and set aside at any time if it is shown that petitioner, knowingly, used information it knew was false, in the application or during the presentation of the evidence at the hearing for the assessment of the application. Any person whose Convenience and Need Certificate has been so voided and set aside shall have the right to request an administrative hearing within a 30 days terms from having been notified as to the setting aside of the certificate.

5- Any holder of a Convenience and Need Certificate shall have to notify S.A.R.A.F.S. as to its intention of closing operations six (6) months before suspending the service. If the intention of the closing is temporary the holder of the Certificate shall have to notify the time estimated during which it will not be offering the services and the reason for the same.

6- No health facility may, after having initiated operations, remain closed for a space longer than twelve (12) months. Once said term has elapsed, the Department of Health could cancel the Certificate, prior notice to the holder of the same.

Article X – MISCELLANEOUS PROVISIONS

1- Derogatory Clause – This Regulation sets aside any rule, procedure or part thereof that would be in conflict herewith, in particular it expressly sets aside the Regulation of the Secretary of Health No. 56, filed at the Department of State on August 15, 1986.

2- Reservation Clause – Any matter not covered herein, shall be decided by the Secretary of Health in accordance

to the laws, regulations, applicable executive orders and everything else that is not foreseen therein, shall be ruled by the sound public administration and principles of public policy now in effect.

3- Disclaimer – Any provisions of this Regulation or any other amendments of the same made in the future, that are declared null and void or unconstitutional by a legal authority with jurisdiction, shall not affect the effectiveness and validity of the other provisions, but their effect shall limit to the words, paragraph, sentence, Article or part specifically affected.

4- This Regulation shall become effective within 30 days as of its filing at the Department of State, in accordance to the provisions of Act No. 170 of August 12, 1988, as amended.

APPROVAL DATE: February 20, 2004.

/sgd./ JOHNNY RULLÁN, MD, FACPM
SECRETARY OF HEALTH

2

No. 05-585

IN THE

Supreme Court of the United States

ROSA PÉREZ-PERDOMO,
Secretary, Puerto Rico Health Department,

Petitioner,

v.

WALGREEN CO., WALGREEN OF SAN PATRICIO, INC.
and WALGREEN OF PUERTO RICO, INC.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

BRIEF IN OPPOSITION

YOLANDA BENITEZ DE ALEGRÍA
YOLANDA BENITEZ
LAW OFFICES P.S.C.
1750 Loíza Street
San Juan, PR 00911
(787) 620-6020

HENRY C. DINGER, P.C.
Counsel of Record
STEPHEN D. POSS, P.C.
GOODWIN PROCTER LLP
Exchange Place
Boston, MA 02109
(617) 570-1000

Attorneys for Respondents

198236

COUNSEL PRESS
(800) 274-3321 • (800) 359-6859

QUESTION PRESENTED

Whether 24 P.R. Laws Ann. § 334 *et seq.* violates the dormant commerce clause by requiring a certificate of necessity and convenience to open a retail pharmacy in the Commonwealth of Puerto Rico where the statute (i) directs the government to deny a certificate when the new pharmacy will "unduly affect existing" pharmacies, (ii) exempts from its operation a great many pharmacies almost all of which are locally owned, and (iii) is applied to deny a certificate only when a competing pharmacy objects.

RULE 29.6 CORPORATE DISCLOSURE STATEMENT

Respondent, Walgreen Co., is a publicly held corporation. Walgreen Co. has no parent corporation and there is no publicly held corporation that owns more than 10% of the stock of Walgreen Co.

Respondents, Walgreen of San Patricio, Inc. and Walgreen of Puerto Rico, Inc., are both wholly owned subsidiaries of Walgreen Co.

TABLE OF CONTENTS

Contents

TABLE OF CITED AUTHORITIES

Cited Authorities

COUNTERSTATEMENT OF THE CASE

Introduction

This case presents no important issue of law and no conflict among the circuit courts. The court below applied long-recognized principles of commerce clause law to a unique set of circumstances not replicated anywhere else in the Nation. There is no reason whatever for this Court to grant review.

The case involves the application of Puerto Rico's "certificate of need" ("CON") legislation to retail pharmacies. Although CON legislation has been adopted by many States to regulate the establishment of new hospitals and other capital-intensive medical facilities, Puerto Rico is unique among U.S. jurisdictions in applying its CON legislation to retail pharmacies. The record below demonstrates that it does so to protect locally owned pharmacies from competition from national retailers. Before issuing a CON — which Puerto Rico calls a "certificate of necessity and convenience" ("CNC") — the Puerto Rico Secretary of Health must certify that the proposed pharmacy will not "unduly affect the existing services." 24 L.P.R.A. § 334(e). Petitioner acknowledges that the government gives serious scrutiny to a CNC application only when an existing pharmacy objects to its issuance. Unopposed applications are invariably granted.

The court of appeals found this law, as applied to retail pharmacies, to be "protectionist both *de jure* and *de facto*," Pet. App. 11, and ruled that it violated the dormant commerce clause. Petitioner points to no decision — of this or any other court — that is inconsistent with this ruling.

Petitioner's principal argument is that federal legislation that was repealed nearly twenty years ago approved the discrimination against interstate commerce that the Puerto Rico law practices. Petitioner raises this argument for the first time in this petition. Since she did not raise this argument below, it is waived. The argument is, moreover, plainly wrong. Petitioner acknowledges that, under this Court's precedent, federal legislation can validate otherwise unconstitutional discrimination against interstate commerce only where Congress' intent to validate has been made "unmistakably clear." *South-Central Timber Dev., Inc. v. Wunnicke*, 467 U.S. 82, 91 (1984). Petitioner points to nothing in any federal statute that authorizes discrimination in favor of local businesses at all, much less language that provides the requisite "unmistakable clarity." In any event, the legal question that petitioner urges this Court to review is so unusual — reliance on long-repealed federal law to justify discriminatory legislation — and so fact-specific — Puerto Rico is the only U.S. jurisdiction that regulates retail pharmacies in this fashion — that there is no warrant for review by this Court.

Petitioner further argues that there was insufficient evidence of record to support the court of appeals' conclusion that the Puerto Rico statute was in fact protectionist. Walgreens disagrees with petitioner's assessment of the evidence, but more to the point, a mere disagreement concerning inferences from the record does not warrant review by this Court.

Certificate of Need Legislation

Petitioner suggests that the decision below threatens to invalidate certificate of need laws that exist in a substantial number of States. This is entirely untrue for a number of reasons, explained below. We begin, however, with a description of the federal legislation (now repealed) that prompted many states, and Puerto Rico, to enact certificate of need laws.

In the mid-1970's, Congress enacted the National Health Planning and Resources Development Act, Pub. L. No. 93-641, 88 Stat. 2225 (1975). This legislation obliged each State (as a condition to receiving federal health care funding) to establish a CON program. Such programs were to review proposed health care services and major capital expenditures on health care facilities and to approve only those projects that were consistent with federal criteria. *See, e.g., id.* § 1512(B)(3)(B) (listing powers of regional councils). *See also* P. McGinley, "Beyond Health Care Reform: Reconsidering Certificate of Need Laws in a 'Managed Competition' System," 23 FLA. ST. U.L. REV. 141 (1995).

The congressional purpose for requiring CON programs was primarily one of moderating the ever-escalating cost of health care in the United States. *See* Pet. App. 25; McGinley, *supra*, 23 FLA. ST. U.L. REV. at 148. Congress perceived that, because of imperfections in the market for medical and diagnostic services, market forces alone would not check "over-investment" in expensive, specialized health care facilities. A significant imperfection was that the owners of such facilities — typically physicians or institutions run by physicians — had the ability to create artificial demand by prescribing unnecessary hospitalizations and medical

procedures (for which tax-funded programs such as Medicare often paid) in order to keep beds filled and equipment fully utilized. *See id.* at 148-56. For example, a hospital that installed an expensive MRI device would be able to recover its substantial capital investment and ongoing maintenance expenses only by ensuring a steady stream of patients needing MRIs. The hospital itself could generate the necessary demand for MRIs simply by finding occasion to prescribe them. Having "too many" health care facilities would, it was thought, result in unnecessary utilization for which taxpayers ultimately would pay. Congress hoped that requiring health care providers to demonstrate the existence of genuine need for new facilities before their establishment would ensure a more rational and efficient match between supply and demand.

Twelve years later, Congress repealed the CON requirement, concluding that it had not worked. Nevertheless, many States continue to require certificates of need for major new health care facilities.

Two aspects of the 1975 federal legislation should be noted. First, Congress never required that States include pharmacies in their CON legislation and, with the exception of Puerto Rico, no U.S. jurisdiction did. Pet. App. 28. It apparently never occurred to anyone to do so because the retail pharmacy market does not suffer from the market imperfections that prompted Congress to act. Pharmacies are not typically owned or managed by physicians. Because only physicians can prescribe prescription drugs, the owners of retail pharmacies cannot artificially create demand. Moreover, the retail pharmacy market does not depend upon expensive, highly specialized capital investments. Petitioner has never contended that its application of its CON law to pharmacies reduces the cost of prescription drugs. Nor could

such contention plausibly be made. As the Fourth Circuit observed in a similar case, "[w]ithout rate regulation, higher rather than lower prices will more likely result from limiting competition." *Medigen of Ky., Inc. v. Pub. Serv. Comm'n of W. Va.*, 985 F.2d 164, 167 (4th Cir. 1993).

Second, there is nothing in the federal legislation — and petitioner points to nothing — that suggests that States were authorized to discriminate in favor of local health care providers in implementing their CON laws and regulations.

The Puerto Rico Legislation

In 1975, Puerto Rico enacted CON legislation in response to the federal statute discussed above. 24 L.P.R.A. § 334 *et seq.* (the "CNC Act"). Pet. App. 54-74. The CNC Act defines a certificate of necessity and convenience as a

> document issued by the Secretary of Health authorizing a person to carry out any of the activities covered by [the Act], certifying that the same is necessary for the population it is to serve and *that it will not unduly affect the existing services*, thus contributing to the orderly and adequate development of health services in Puerto Rico.

§ 334(e) (emphasis added). Under the CNC Act, no person may acquire or construct a new "health facility" without a CNC. § 334a.

When originally enacted, the CNC Act did not apply to pharmacies. Four years later, the Puerto Rico legislature amended the Act to include "pharmacies" in the definition of "health facilities" to which the Act applied. There is no legislative history to this amendment. However, in the years

leading up to this amendment, Walgreens opened 12 pharmacies in Puerto Rico. Pet. App. 28. Although this represented a tiny proportion of the approximately 850 retail pharmacies in Puerto Rico in 1979, it was a threat of more competition from national chains to come.[1] Significantly, all of these pre-existing pharmacies were protected by a provision that entitled them to a CNC "without the requirement of the determination of public necessity and convenience and without the holding of a hearing." § 334g.

Although this group of overwhelmingly local pharmacies did not themselves have to demonstrate that their facilities were necessary or convenient, they were given the right to object to any prospective competitor that sought to open a pharmacy within their so-called "service area," defined in the implementing regulations as a one-mile radius. The CNC Act requires that such local pharmacies be notified of any CNC application in their area, and entitles them to submit evidence in opposition and challenge in the courts any CNC that does issue. The record below demonstrated that local pharmacies frequently took advantage of these procedures.

The opposition of local pharmacies to CNC applications plays a major role in the operation of the CNC Act. The opposition of a local pharmacy always delays, and often

---

1. The *Asociacion de Farmacias de la Comunidad*, a trade association of pharmacies in Puerto Rico that limits membership to pharmacies in which the majority shareholders are residents of Puerto Rico, unsuccessfully sought to intervene in this case to defend the constitutionality of the CNC Act. The *Asociacion* has consistently advocated for the inclusion of pharmacies in the CNC Act, despite the considerable administrative burdens that the Act imposes on its members. Pet. App. 28-29. That in itself is powerful evidence that the CNC Act is protectionist, as this Court has observed. *See Hunt v. Wash. Apple Adver. Comm'n.*, 432 U.S. 333, 352 (1977).

prevents, national retailers from opening a competing pharmacy. Moreover, the uncontroverted statistical evidence adduced at trial clearly suggests the existence of a double standard in the application of the CNC Act. Local pharmacies seeking CNCs are almost invariably successful, receiving CNCs 97% of the time, including a 90% success rate even when there is opposition from other pharmacies. However, when there is opposition to a national retailer's CNC application, the application is denied almost as often as it is allowed.

Proceedings Below

Contrary to petitioner's suggestion, Pet. 6, the case was not decided on cross-motions for summary judgment. Rather, the parties consented to a trial by the district court on a stipulated written record that consisted largely of undisputed statistical evidence concerning the application of the CNC Act and expert testimony. *See* Pet. App. 7 n.2. The district court and the court of appeals accepted the uncontested evidence that "local pharmacies are granted a CNC at a much higher rate than their out-of-state counterparts." Pet. App. 45.

The district court concluded that the statistical evidence alone was an insufficient basis to conclude that the CNC Act discriminated against non-local applicants. However, the court of appeals ruled that the statistical evidence, combined with (i) the exemption of a large group of almost entirely local pharmacies from the requirements of the CNC Act, (ii) the consistent practice of enforcing the Act only if an existing pharmacy opposes a CNC application, and (iii) the Act's direction that the Secretary of Health deny a CNC if the new pharmacy would "unduly affect" existing pharmacies in the area, compelled the conclusion that the Act discriminated against interstate commerce. Pet. App. 10-11.

The First Circuit then considered whether petitioner had justified the discrimination "both in terms of the local benefits flowing from the statute and the unavailability of nondiscriminatory alternatives adequate to preserve the local interests at stake." Pet. App. 18 (quoting *Hunt v. Wash. Apple Adver. Comm.*, 432 U.S. 333, 353 (1977)). Petitioner had made no attempt to justify its implementation of the CNC Act's pharmacy provisions with reference to the cost saving rationale of the federal CON legislation. The experts below all acknowledged that limiting competition, as the CNC Act does, reduces pressure to moderate the prices charged for prescription drugs. The only justification that petitioner advanced was that by denying CNCs in areas already served by pharmacies, the government would encourage the establishment of pharmacies in "underserved" regions. However, the court of appeals noted that the experts on both sides agreed that the Act cannot reasonably be thought to advance that interest. Pet. App. 18. Denying a CNC applicant the ability to establish a pharmacy in a profitable location does nothing to make a different, unprofitable location more attractive.

REASONS FOR DENYING THE PETITION

Petitioner does not contend that the decision below conflicts with any decision of this Court or of any other federal or state appellate court. To the contrary, there have been many decisions over the years that have struck down state laws that impose disproportionate barriers to market entry on non-local businesses. *See, e.g., C&A Carbone, Inc. v. Town of Clarkstown*, 511 U.S. 383, 391 (1994); *H.P. Hood & Sons, Inc. v. DuMond*, 336 U.S. 525, 545 (1948); *Buck v. Kuykendall*, 267 U.S. 307, 314-16 (1925); *McNeilus Truck & Mfg., Inc. v. Ohio*, 226 F.3d 429, 441-44 (6th Cir. 2000). Petitioner does not identify a single decision of any court that is inconsistent with the First Circuit's decision below.

Petitioner does suggest that the questions presented are "important question[s] of federal law that ha[ve] not been, but should be, settled by" this Court. Sup. Ct. R. 10(c). However, neither of the questions set forth in the petition satisfies this criterion.

I. The Question Concerning the Effect of the Long-Repealed National Health Planning and Resources Development Act of 1974 on Discriminatory Certificate of Need Laws was Not Raised Below and Presents No Important Issue that Requires Resolution by this Court.

Petitioner's first question, to which she devotes the bulk of the petition, is whether the National Health Planning and Resources Development Act of 1974 (the "1974 Act") "insulates" the CNC Act from commerce clause scrutiny. Petitioner argues that by imposing the obligation on States to adopt CON legislation, Congress permitted the States to act in a manner that would otherwise violate the commerce clause. *See* Pet. 10.

At the outset, review of this question is unwarranted because petitioner has raised it for the first time in her petition. She made no such argument in either the district court or the court of appeals. As a result, petitioner has waived any right to press it. *See Brown v. Socialist Workers '74 Campaign Comm.*, 459 U.S. 87, 104-105 (1982); *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 147 n.2 (1970); *Lawn v. United States*, 355 U.S. 339, 362 n.16 (1958) ("Only in exceptional cases will this Court review a question not raised in the court below.").

Moreover, even if petitioner could raise this issue, review is in no way warranted under the standards followed by this Court.

Petitioner's first question has two parts. The first is whether the 1974 Act did in fact authorize Puerto Rico to discriminate in favor of local pharmacies in the CNC Act. The legal standard that governs this question is not a matter of controversy. This Court has made it clear that since the commerce clause is a grant of regulatory and legislative power to Congress, Congress can permit States to regulate commerce in a manner that would not otherwise be permitted. It is equally well-settled that courts will not lightly infer such authorization, but will require that Congress set forth its intent to do so in a manner that is "unmistakably clear." *South-Central Timber*, 467 U.S. at 91. Petitioner acknowledges this principle. Pet. 10.

However, one searches the petition in vain for the identification of any language in the 1974 Act or its legislative history that expresses *any* intent to permit discrimination against interstate commerce in the implementation of CON statutes, much less anything that rises to the level of unmistakable clarity. Petitioner is content simply to say that Congress "required" CON laws. Pet. 11.

Petitioner begs the question. There is nothing in the 1974 Act or its legislative history that even remotely supports the notion that the CON requirement — a device intended to reduce the costs of health care nationally — could be used to protect local health care providers, much less pharmacies, from competition from out-of-state businesses.

The statute's only possible reference to pharmacies — which the Secretary notes only in passing, Pet. at 11 n.6 — is that the definition of a "provider of healthcare" includes persons who "produc[e] or suppl[y] drugs . . . for individuals" or an entity that "produc[es] drugs." 1974 Act § 1531(3)(B)(II). Even if this definition were read to refer to pharmacists, it plainly does not constitute the unmistakably clear support for the

discrimination practiced by the CNC Act. This definition was included for a quite different purpose: to limit the influence of "providers of healthcare" in the regulatory process.

The 1974 Act was to be administered, in large measure, by a series of councils — federal, § 1503, regional, § 1511, and state, § 1524 — that would review CON applications and distribute funds. *See, e.g.*, § 1512(B)(3)(B) (listing powers of regional councils). The membership of each council was carefully balanced among representatives of various interest groups. For example, of the twelve voting members of the federal council, not more than three could be federal employees; no fewer than three could be members of state councils; and Democrats and Republicans had to be equally balanced. § 1503(B)(1). The statute also sought to prevent providers of health care from dominating the councils by ensuring that "persons who are not providers of health services" were guaranteed five seats.[2] *Id.*

The legislative history confirms that the purpose for defining "providers of healthcare" was to delineate the composition of the various regulatory councils. As the Senate Report explained:

> The intent of the definition of "providers of health services" contained in the proposed legislation is to include any individual with an existing or potential conflict of interest with respect to the recommendations of the health planning agency. Although the committee recognizes the valuable contributions providers of health services can and

2. A similar limitation on industry representation is required at the regional, § 1512(B)(3)(C)(I) ("a majority" of seats must be held by "consumers of health care . . . who are not . . . providers of health care") and state, § 1524(B)(1)(A)(III) (same), levels, too.

> must make to the health planning process, it also believes that if the plan which emerges is to be viable, their influence on the health planning process must be appropriately limited.

S. Rep. No. 93-1285, at 7885 (1974), *as reprinted in* 1974 U.S.C.C.A.N. 7842.

There is absolutely nothing in the 1974 Act or its legislative history that suggests that Congress contemplated that the States would require pharmacies to obtain CONs. Since pharmacies are in no position artificially to increase demand for the products they sell, the market imperfections that prompted Congress to enact CON legislation do not exist in the retail pharmacy market. As a result, no State has ever required pharmacies to obtain CONs. *A fortiori*, there is nothing in the statute that could plausibly be read to permit States to favor local pharmacies in processing CON applications. Since there is no indication *at all* that Congress endorsed such discrimination, petitioner cannot possibly demonstrate such intent with unmistakable clarity.

This Court has refused to find Congressional approval of protectionist State legislation under far more compelling circumstances than those presented here. In *South-Central Timber*, for example, the State of Alaska prohibited the export of unprocessed logs taken from lands owned by the State, but required, as a condition of export, that the logger process the timber in Alaska. A logging company challenged the regulation as a violation of the commerce clause. The State defended by observing that the federal government imposed a similar policy on timber taken from federal land, including federal land in Alaska. The State argued that this reflected Congress' approval of local processing requirements.

This Court rejected the argument, finding that the approval of a "parallel policy" did not constitute a clear and unmistakable approval of any State pursuing the same policy. If there were no "unmistakably clear" authorization for State action that violated commerce clause principles in *South-Central Timber*, then *a fortiori* there is no such authorization in this case, where there is neither express authorization for the violation in the 1974 Act, nor supportive language in its legislative history, nor any "parallel" federal policy. *See also C&A Carbone, Inc.*, 511 at 409 (O'Connor, J., concurring) (in spite of references in statute and legislative history "indicat[ing] that Congress expected local governments to implement some form of flow control," these "neither individually nor cumulatively r[o]se to the level of the 'explicit' authorization required by [the Court's] dormant Commerce Clause decisions.").

But even if there were something in the 1974 Act that lent colorable support to petitioner's claim that Congress blessed its protectionism, Congress repealed the 1974 Act nearly twenty years ago. If the 1974 Act shielded Puerto Rico from a commerce clause challenge to the CNC Act, then Congress removed the shield long before Walgreens commenced this litigation.

Petitioner posits that since Congress did not specifically address "what would happen with state CON laws" when it repealed the 1974 Act, "the only reasonable way to interpret what Congress intended is to conclude that it did not wish to change its earlier authorization of such laws." Pet. 12. This is nonsense. A repeal is a repeal. The only reasonable inference is that Congress intended to eliminate whatever effect Congress sought to achieve when it enacted the 1974 Act. Had it wished to preserve some requirement or

protection enacted as part of the 1974 Act, Congress would not have repealed the pertinent portion of the Act.

Petitioner also suggests that the First Circuit's decision calls into question the validity of CON legislation throughout the country. But the court of appeals did nothing of the sort. Both Walgreens' challenge and the First Circuit's ruling were expressly limited to the application of the CNC Act to retail pharmacies. The court's holding in this regard is unambiguous: "For the foregoing reasons, [the CNC Act] *as enforced by the Secretary of Health for the issuing of certificates of necessity and convenience to retail pharmacies*, is invalid under the dormant Commerce Clause." Pet. App. 19 (emphasis added). Nothing in the decision below precludes Puerto Rico (or any State) from continuing to apply the CNC Act to hospitals, nursing homes, diagnostic and treatment centers, blood banks, and the other "health facilities" identified in the Act.

Because the ruling was limited to retail pharmacies, it will have *no* effect on the CON laws of any State. Puerto Rico is the only U.S. jurisdiction that applies its CON legislation to pharmacies.

Petitioner argues in a footnote that "[t]he reasoning used by the Court of Appeals for invalidating the CNC Act is equally applicable to *all* CON programs nationwide, regardless of the type of health facility that they regulate." Pet. 11 n.6. Petitioner reads more into the First Circuit's decision than it will bear.

The First Circuit plainly did not rule that the principles that underlie CON legislation in general to be in any way inconsistent with the commerce clause. The "market imperfection" rationale for CON legislation does not apply to the retail pharmacy market. No other CON law applies to pharmacies. The court of appeals merely ruled that Puerto Rico could not regulate pharmacies in a way that served primarily to

protect local pharmacies from competition from national retail chains. There is absolutely nothing in the record in this case to suggest that any other jurisdiction uses its CON legislation in such a protectionist fashion, or that Puerto Rico applies the CNC Act in a protectionist fashion with respect to any other kind of facility. In the absence of evidence of such abuse of the CON process, the First Circuit's decision in this case will afford no help to those who seek to invalidate CON laws.

II. Petitioner's Second Question Merely Challenges the Inferences that the Court Drew from the Record and Does Not Present a Question that Warrants Review by this Court.

Petitioner's second question presents no unsettled question of law. Petitioner does not contend that the First Circuit applied incorrect legal principles. Her contention is that in applying those principles to the largely undisputed evidence in the record, the First Circuit reached the wrong conclusion. Petitioner's contention in this regard is incorrect, but even if she were right, her second issue does not warrant review by this Court.

Petitioner's principal argument appears to be that the First Circuit placed undue emphasis on the facts that the CNC Act insulated the more than 800 pharmacies already established in Puerto Rico when the Act was passed from being required to prove that their pharmacies were necessary and convenient, and that all but a dozen of these pharmacies were locally-owned. This argument is deeply flawed.

This Court has recognized that a statute's exemptions and exceptions bear on the commerce clause analysis. For example, in *Raymond Motor Transp., Inc. v. Rice*, 434 U.S. 429 (1978), this Court invalidated on commerce clause

grounds a state law that restricted the length and configuration of trucks that could be operated within the state. The Court observed:

> One other consideration, although not decisive, lends force to our conclusion that the challenged regulations cannot stand. As we have noted, Wisconsin's regulatory scheme contains a great number of exceptions to the general rule that vehicles over 55 feet long cannot be operated on highways within the State. At least one of these exceptions discriminates on its face in favor of Wisconsin industries and against the industries of other States, and there are indications in the record that a number of the other exceptions, although neutral on their face, were enacted at the instance of, and primarily benefit, important Wisconsin industries. Viewed realistically, these exceptions may be the product of compromise between forces within the State that seek to retain the State's general truck-length limit, and industries within the State that complain that the general limit is unduly burdensome. Exemptions of this kind, however, weaken the presumption in favor of the validity of the general limit, because they undermine the assumption that the State's own political processes will act as a check on local regulations that unduly burden interstate commerce.

Id. at 446-47 (footnote omitted). The First Circuit considered the evidence of the CNC Act's exemption of pre-existing pharmacies in exactly the same manner as this Court considered the exemptions in *Raymond*, that is, as weakening the petitioner's argument that the statute was neutral. The

inference was particularly strong in this case because the Act not only exempted a huge number of overwhelmingly local pharmacies from the Act's operation, but also directed the Secretary to deny CNCs when a proposed new pharmacy would "unduly affect" them.

Petitioner posits that "[t]his Court has consistently validated the inclusion of grandfather clauses within the regulatory schemes for the issuance of certificates of necessity and convenience." Pet. 22. However, the only support advanced for this proposition are two cases involving grandfather clauses in *federal* regulatory schemes.[3] Obviously, limitations on *state* power imposed by virtue of this Court's dormant commerce clause jurisprudence have no effect on the actions of the federal government.

The First Circuit did not rule that "grandfather clauses" are *per se* invalid or in themselves establish a violation of the commerce clause. The court merely gave weight to the fact that local pharmacies were exempted in large numbers from burdens imposed on newcomers just as national retail chains were beginning to enter what had been an entirely local industry. In light of the other evidence — the stark statistical disparity in success rates enjoyed by local pharmacies as opposed to national chains in the CNC process, the vehement support of local pharmacies for the CNC Act, and the provision of the Act that directed petitioner to insulate existing pharmacies from unwanted competition — the First Circuit's conclusion was entirely logical and defensible. In any event, there is no reason to think that this unusual combination of factual circumstances is likely to be repeated.

---

3. *Crescent Express Lines v. United States*, 49 F. Supp. 92 (S.D.N.Y. 1943), *aff'd*, 320 U.S. 401 (federal Motor Carrier Act); *United States v. Carolina Freight Carriers Corp.*, 315 U.S. 475 (1942) (same).

It is not a wise use of this Court's very limited time to review a case to decide whether there was sufficient evidence to sustain a conclusion based on the application of settled and undisputed legal principles. That is all that petitioner's second issue invites this Court to undertake.

CONCLUSION

The petition in this case asks this Court to review (i) an issue never raised below that is unlikely ever to arise in any other case, and (ii) the sufficiency of the evidence to sustain the conclusion reached by the court below based on unchallenged and well-established principles of law. Neither question presented warrants this Court's attention. The petition should be denied.

Respectfully submitted,

HENRY C. DINGER, P.C.
Counsel of Record
STEPHEN D. POSS, P.C.
GOODWIN PROCTER LLP
Exchange Place
Boston, MA 02109
(617) 570-1000

YOLANDA BENITEZ DE ALEGRÍA
YOLANDA BENITEZ
LAW OFFICES P.S.C.
1750 Loíza Street
San Juan, PR 00911
(787) 620-6020

Attorneys for Respondents

(5)

No. 05-585

IN THE

Supreme Court of the United States

ROSA PÉREZ-PERDOMO, in her official capacity as Secretary of Health of the Commonwealth of Puerto Rico,
Petitioner,

v.

WALGREEN CO.; WALGREEN OF SAN PATRICIO; and WALGREEN OF PUERTO RICO,
Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the First Circuit

REPLY BRIEF FOR THE PETITIONER

MIGUEL A. SANTANA-BAGUR *
Deputy Attorney General of Puerto Rico

SALVADOR J. ANTONETTI-STUTTS
Solicitor General of Puerto Rico

MARIANA D. NEGRÓN-VARGAS
Deputy Solicitor General

MAITE ORONOZ-RODRÍGUEZ
Deputy Solicitor General

DORALIZ E. ORTIZ-DE-LEÓN
Assistant Solicitor General
Department of Justice
P.O. Box 9020192
San Juan, Puerto Rico 00902-0192
(787) 724-2165 Ext. 2707

* Counsel of Record

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20001

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statute

This case does present important issues of law as to which there is substantial dispute, and which call for review by this Honorable Court. Indeed, perhaps the best evidence that the first question presented is hotly disputed is furnished by Respondents' own brief, a considerable portion of which is dedicated to arguing that the repeal of the National Health Planning and Resource Development Act of 1974, Pub. L. No. 93-641, 88 Stat. 2225 (repealed 1986) (the "1974 Act"), divested the States of any protection they would otherwise have had from challenges pursuant to the Commerce Clause. That Respondents so strongly disagree with Petitioners on this point should tip the balance in favor of the grant of the petition for a writ of certiorari.

As a procedural matter, this Court is clearly permitted to review the first question presented; namely, whether the 1974 Act shields the CNC Act from Commerce Clause scrutiny.[1] Although Respondents are correct in noting that Petitioner did not fully develop this argument below, this Court has the authority and discretion to consider any theory related to an issue that was raised below, and will do so whenever the question is important enough. *Singleton v. Wulff*, 428 U.S. 106, 120-21 (1976); *Hormel v. Helvering*, 312 U.S. 552, 556 (1941). As the Sixth Circuit recently summarized the matter,

> First, we may deviate from the general rule if this is an exceptional case, if declining to review issues for the first time on appeal would produce a plain miscarriage of justice, or if this appeal presents a "particular circumstance" warranting departure. . . . We also may hear an issue for the first time on

---

[1] Please note that there is no doubt at all that the second question presented was fully briefed and argued both in the District Court and the Court of Appeals.

> appeal if doing so would serve an overarching purpose other than simply reaching the correct result in this case. . . . Finally, we should address an issue presented with sufficient clarity and requiring no factual development if doing so would promote the finality of litigation in this case.

In re Morris, 260 F.3d 654, 120-21 (6th Cir. 2001) (citations omitted). As argued below, this case presents particular circumstances that call for review, including not only that consideration of the questions presented serve overarching purposes that go beyond the result in this case (because they have the potential to affect all other States' CON laws) but also that the question is clearly-defined and requires no additional factual development in order for it to be resolved.

Every stage of this litigation has revolved around the issue whether the CNC Act runs afoul of the dormant Commerce Clause doctrine; only the degree of emphasis placed on different arguments has varied. Petitioners have consistently argued that the Commerce Clause is not meant to be used as a mechanism for encroaching upon legislative matters and inquiring into the motive, policy, wisdom or expediency of state legislation. In sum, this Court can and should decide whether a federal circuit court is permitted to engage in dormant Commerce Clause scrutiny and invalidate a state law that was clearly sanctioned by Congress.

Respondents' other argument against the grant of certiorari with respect to the first question presented is to deny that the 1974 Act authorized the States to adopt discriminatory policies in the first place. Respondents' argument is formally valid - if their premise were correct, then the repeal of the 1974 Act would not raise any interesting or important questions of law. Fortunately, the

premise is incorrect, for the 1974 Act did authorize the States to adopt discriminatory laws and regulations.

Respondents concede that the 1974 Act *obliged* each State to establish a CON program (Opp. 3), but fail to recognize what their concession means. In that regard, although it is absolutely true that in order "for a state regulation to be removed from the reach of the dormant Commerce Clause, congressional intent must be unmistakable clear." *South-Central Timber Development, Inc. v. Wunnicke,* 467 U.S. 82, 91 (1984) (Opp. 2, 10, 12, 13), Respondents' reliance on *Wunnicke* is misplaced because it is distinguishable on its facts from this case.

In *Wunnicke*, the State of Alaska argued that its statutory requirement that timber taken from state lands be processed within the State prior to export was insulated from Commerce Clause scrutiny because the policy had been implicitly authorized by a similar federal policy that applied only to timber taken from federal land. This Court explained, however, that the fact that Congress acted only with respect to federal lands was insufficient to indicate that it intended to authorize a similar policy with respect to state lands. *Id.* at 92-93.

In contrast, in the instant case the congressional intent to insulate the CNC Act from Commerce Clause scrutiny is "unmistakably clear." As noted by Respondents, Congress *obliged* each state (as a condition to receiving federal health care funding) to establish CON programs (Opp. 3). Moreover, one only needs to read the definition of "provider of health care" in the CNC Act to corroborate that Congress intended pharmacies to be regulated by state CON programs. *See* 1974 Act § 1531(3)(B)(III).[2] In sum, even if there were

---

[2] It is simply wrong for Respondents to claim that the only "purpose for defining 'providers of health care' was to delineate the composition of

something in the CNC Act indicative of discrimination, the fact is that Congress not only allowed it, but also encouraged it, by requiring the States to enact CON programs in order to receive federal funds.

In addition, however, with respect to the first question presented, Petitioners contend that the CNC Act does *not* discriminate against interstate commerce, and that in reaching the opposite conclusion, the First Circuit clearly misapplied Supreme Court precedent, which is another reason for granting the petition for a writ of certiorari in the instant case.

Indeed, it is telling that Respondents do not mention any precedent in support of their theory that the reason why CNC Act is discriminatory is simply because it allows the Commonwealth "to deny a certificate when the new pharmacy will 'unduly affect existing' pharmacies." (Opp. *i*). One of the goals of the 1974 Act was precisely to oversee the adequate market distribution of health facilities and services. In order to achieve this purpose, the 1974 Act provided that "only those services, facilities, and organizations found to be *needed*" would be offered or developed in the States. *See* 1974 Act § 1523(4)(A) (emphasis added). Hence the name "certificate of need." As a result, CON programs nationwide invariably require providers of health care to show the market feasibility of the proposed service in the proposed location.[3]

---

the various regulatory councils." (Opp. 11). Although Respondents are free to craft their own theories about the legislative intent behind the 1974 Act, the plain language of the statute shows that Congress meant CON programs to apply to "providers of health care," and that this term includes pharmacies.

[3] Respondents also err in arguing that the fact that the *Asociación de Farmacias de la Comunidad* "has consistently advocated for the inclusion of pharmacies in the CNC Act, despite the considerable

Oddly enough, the best example of the First Circuit's misapplication of Supreme Court precedent (and thus, of the need for Supreme Court review) is to be found in Respondents' own brief, which places much emphasis on the fact that "[t]he First Circuit considered the evidence of the CNC Act's exemption of pre-existing pharmacies in *exactly the same manner* as this Court considered the exemptions in *Raymond Motor Transp., Inc. v. Rice*, 434 U.S. 429 (1978), that is, as weakening the petitioner's argument that the statute was neutral." (Opp. 16, emphasis added). The First Circuit clearly erred by applying the holding in *Raymond* in order to invalidate the CNC Act.

The maze of statutory and administrative exemptions that rendered invalid the statute at issue in *Raymond* are not even remotely similar to the single exemption of the CNC Act that is being challenged here: the grandfather clause. As noted by this Court, the number and type of exemptions in *Raymond* undermined the statute's alleged safety purpose because they routinely resulted in the grant of permits to vehicles that were undistinguishable from those of plaintiffs'

---

administrative burdens that the act imposes on its members" is, in itself, "powerful evidence that the CNC Act is protectionist." (Opp. n.1). To the contrary, these facts do *not* support an inference of discrimination; as Justice O'Connor remarked in a concurring opinion:

> The existence of substantial in-state interests harmed by a regulation is a 'powerful safeguard' against legislative discrimination. The Court generally defers to health and safety regulations because 'their burden usually falls on local economic interests as well as other States' economic interests, thus insuring that a State's own political processes will serve as a check against unduly burdensome regulations.

C & A Carbone, Inc. v. Town of Clarkstown, 511 U.S. 383, 404 (1994) (citations omitted).

in terms of size, safety and divisibility of loads. *Id.* at 791. There simply was no way to view these laws and regulations as serving neutral objectives; to the contrary, it was fairly obvious that they sought only to protect in-state interests.

In sharp contrast, the grandfather clause of the CNC Act is neutral and serves a rational and legitimate purpose: mainly to avoid unfair results and the possibility of due process violations to those health facilities that were already established at the time of enactment of the CNC Act. Thus, the grandfather clause of the CNC Act, unlike the numerous exemptions at issue in *Raymond,* is simply *not* indicative of discrimination against interstate commerce.

Finally, it is incorrect for Respondents to state that the purpose of the petition for a writ of certiorari is to review the First Circuit's interpretation of the evidence on record. (Opp. 18). The questions presented for review by Petitioner are questions of law that challenge the First Circuit's misapplication of the dormant Commerce Clause doctrine to the CNC Act.[4]

Finally, Respondents miss the mark in attempting to downplay the national importance of this case. For example, Respondents suggest that CON legislation is consistent with the commerce clause: "the First Circuit plainly did not rule that the principles that underlie CON legislation in general to be in any way inconsistent with the commerce clause." (Opp. at 14). By this, they seek to limit the First Circuit's

---

[4] As mentioned by Respondents, the District Court did not decide the instant case on cross motions for summary judgment, but instead "the parties consented to a trial by the district court on a stipulated written record that consisted largely of undisputed statistical evidence concerning the application of the CNC Act and expert testimony." (Opp. 7). Although this statement is procedurally correct, it has no practical effect on the outcome of the case because the questions at issue are of law and not of fact.

decision to its facts, and thus, to make this case less likely to be deemed worthy of review.

The attempt should fail. Petitioner agrees with Respondents that CON laws are valid under the dormant Commerce Clause. Nevertheless, she firmly disagrees with the use to which Respondents put this conclusion because, for purposes of Commerce Clause analysis, and contrary to Respondents' contention, there is no material difference between the CNC Act and other States' CON laws. Thus, if other States' CON laws are valid under the dormant Commerce Clause, then so should the CNC Act, and vice-versa: if the First Circuit was correct in holding that the CNC Act was invalid, then so are the other States' CON laws. Respondents cannot plausibly deny that this is an important issue of law.[5]

CONCLUSION

For the foregoing reasons, and for those set forth in the petition, the petition for a writ of certiorari should be granted.

RESPECTFULLY SUBMITTED.

MIGUEL A. SANTANA-BAGUR
Deputy Attorney General of Puerto Rico
Counsel of Record

SALVADOR J. ANTONETTI-STUTTS

---

[5] As this Court is aware, the American Health Planning Association (AHPA), the only national organization representing regional and state agencies engaged in the administration of state CON programs, filed an Amicus Brief in support of the petition for a writ of certiorari. The AHPA is not as sanguine as Respondents about the national impact of the First Circuit's ruling in this case.

Solicitor General of Puerto Rico

MARIANA D. NEGRÓN-VARGAS
Deputy Solicitor General

MAITE ORONOZ-RODRÍGUEZ
Deputy Solicitor General

DORALIZ E. ORTIZ-DE-LEÓN
Assistant Solicitor General
Department of Justice
P.O. Box 9020192
San Juan, Puerto Rico 00902-0192
Tel. (787) 724-2165 Ext. 2707
Fax (787) 724-3380

DEC - 2005

No. 05-585

In The

Supreme Court of the United States

ROSA PEREZ-PERDOMO, in her official capacity as Secretary of Health of the Commonwealth of Puerto Rico,

Petitioner,

v.

WALGREEN CO.; WALGREEN OF SAN PARTRICIO; and WALGREEN OF PUERTO RICO,

Respondents.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The First Circuit

MOTION FOR LEAVE TO FILE BRIEF AND BRIEF *AMICUS CURIAE* OF THE ASOCIACION DE FAMACIAS DE LA COMUNIDAD DE PUERTO RICO IN SUPPORT OF PETITIONER

HARRY ANDUZE MONTANO
Counsel of Record
JOSE MORALES-BOSCIO
1454 Fernández Juncos Ave.
San Juan, PR 00909
Tel. (787) 723-7171
Fax (787) 723-7278

COCKLE LAW BRIEF PRINTING CO (800) 225-6964
OR CALL COLLECT (402) 342-2831

MOTION FOR LEAVE TO FILE BRIEF AS *AMICUS CURIAE*

Pursuant to Supreme Court Rule 37(3)(b), Asociación de Farmacias de Comunidad moves for leave to file the attached brief as *Amicus Curiae* in support of Petitioner, Rosa Pérez-Perdomo, Secretary, Puerto Rico Health Department. Petitioner has consented to the filing of this brief, but Respondents, Walgreen Co.; Walgreen of San Patricio and Walgreen of Puerto Rico, have refused consent, necessitating this motion.[1]

Asociación de Farmacias de Comunidad ("Asociación"), a Puerto Rico nonprofit corporation, is a trade association founded in 1952. Its membership consists of over 750 pharmacies across the Commonwealth of Puerto Rico. Asociación has a long established purpose of ensuring and promoting high-quality health care services to the community.

The issue raised by this case is whether a "Certificate of Need" ("CON") program established in Puerto Rico under the auspices of the National Health Planning and Resources Development Act of 1974, Pub. L. No. 93-641, 88 Stat. 225 (repealed 1986) (the "1974 Act"), and which approximately 37 States still have in force, is repugnant dormant Commerce Clause doctrine. This issue is one of great import to the health care system in Puerto Rico, the beneficiaries of the system, and to the pharmacies community in general.

---

[1] Copy of the consent letter received from Petitioner's counsel was submitted with this Motion and *Amicus Curiae* Brief.

The U.S. Court of Appeals for the First Circuit's decision striking Puerto Rico's statute authorizing its CON program with regards to pharmacies, hampered the Commonwealth's "police power" to further health and welfare objectives embedded in the statute. Asociación therefore has a vital interest in the issue presented in this case, and its views and experience can assist the Court in resolving that issue.

For this reasons, Asociación de Farmacias de Comunidad, respectfully moves for leave to file the attached brief as *Amicus Curiae*.

Respectfully submitted, this 8th day of December, 2005.

HARRY ANDUZE MONTAÑO
1454 Fernández Juncos Ave.
San Juan, PR 00909
Tel. (787) 723-7171
Fax (787) 723-7278

Counsel for Amicus Curiae, Asociación de Farmacias de Comunidad

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page

CASES

TABLE OF AUTHORITIES – Continued

TABLE OF AUTHORITIES – Continued

INTEREST OF THE *AMICUS*[1]

Asociación de Farmacias de Comunidad ("Asociación"), a Puerto Rico nonprofit corporation, is a trade association founded in 1952. Its membership consists of over 750 pharmacies across the Commonwealth of Puerto Rico. Asociación has a long established mission of ensuring and promoting high-quality health care services to the community.

The issue raised by this case is whether a "Certificate of Need" ("CON") program established in Puerto Rico under the auspices of the National Health Planning and Resources Development Act of 1974, Pub. L. No. 93-641, 88 Stat. 225 (repealed 1986) (the "1974 Act"), and which approximately 37 States still have in force, is repugnant to dormant Commerce Clause doctrine. This issue is one of great import to the health care system in Puerto Rico, its beneficiaries, and the pharmacies community in general.

The U.S. Court of Appeals for the First Circuit's decision striking Puerto Rico's statute authorizing its CON program with regards to pharmacies, hampered the Commonwealth's "police power" to further health, safety, and welfare objectives embedded in the statute. Asociación therefore has a vital interest in the issue presented in this

---

[1] Pursuant to this Court's Rule 37.6, *Amicus* states that no counsel for any party authored this brief in whole or in part, and no person or entity other than *Amicus* made a monetary contribution to the preparation or submission of the brief. Counsel of record for Petitioner has consented to the filing of this brief, and the letter of consent has been filed with the Clerk. On the other hand, Counsel of record for Respondents has withheld her consent, thus *Amicus* has filed the corresponding leave to file *amicus* brief.

case, and its views and experience can assist the Court in resolving that issue.

INTRODUCTION AND SUMMARY OF ARGUMENT

The issue raised by this case is whether a "Certificate of Need" ("CON") program established in Puerto Rico under the auspices of the National Health Planning and Resources Development Act of 1974, Pub. L. No. 93-641, 88 Stat. 225 (repealed 1986) (the "1974 Act"), and which approximately 37 States still have in force, is repugnant to dormant Commerce Clause doctrine. This issue is one of great import to the health care system in Puerto Rico, its beneficiaries, and the pharmacies community in general.

In response to the 1974 Act, Puerto Rico enacted the Certificate of Necessity and Convenience Act of the Commonwealth of Puerto Rico (hereinafter "the CNC Act"), 1975 P.R. Laws 2 (codified as amended at 24 P.R. Laws Ann. §§ 334-334j), which required health service providers to show that their services were needed in a particular locale before they commenced servicing the area. In 1979, the CNC Act was amended in order to include pharmacies as "heath care facilities," which were also required to satisfy this showing of need. Law No. 189 of July 29, 1979, amending 24 P.R. Laws Ann. §§ 334 et seq.

Under the CNC petition process, the Secretary of Puerto Rico's Health Department must consider the "present and projected need of the population" affected by the transaction, and the existence of alternatives to the transaction or the possibility of providing the proposed services in a more efficient or less costly manner. 24 P.R.

Laws § 334b. Moreover, the Secretary must examine whether the proposed pharmacy will benefit "unattended populations" (*i.e.*, low-income, disabled or elderly populations), among other criteria. *See* Art. VI of Regulation 56 at Cert. Pet. App. 99 and Art. VII of Regulation 112 at Cert. Pet. App. 162.

Even though the statute's seasoned lifespan, on April 22, 2005, the Court of Appeals struck down the CNC Act understanding that it "impermissibly discriminat[ed] against interstate commerce." *Walgreen Co. v. Rullán*, 405 F.3d 50 (1st Cir. 2005). The basis for such determination was in essence the fact that the statute grandfathered the pharmacies which existed on October 24, 1979 in Puerto Rico, exempting them from the certificate requirement. 24 P.R. Laws Ann. at § 334g. However, the fact that twelve of Respondent's pharmacies benefited from such enactment went unnoticed by the Court. In addition, the Court of Appeals emphasized the fact that the statute authorized that, during a new pharmacy's CNC application process, the existing pharmacies within a one-mile radius of the projected area may file an opposition. *Walgreen Co.*, 405 F.3d at 57. Thereupon, the Court of Appeals engaged in an analysis of several statistics regarding the certificates' issuance purporting to show discrimination intent against interstate commerce – which were the same statistics that the District Court determined were "insufficient to establish a pattern of discrimination." *Walgreen v. Rullán*, 292 F. Supp. 2d 298, 315 (D.P.R. 2003).

Asociación respectfully submits that the Court of Appeals strained its searching look where no sufficient evidence surfaced from the findings before the District Court. Consequently, the Court of Appeals should have applied the balancing test established in *Pike v. Bruce*

Church, Inc., 397 U.S. 137, 142 (1970). But it did not; thus, the case at bar's importance unveils. The Court of Appeals' determination poses a slippery slope for other states' CON programs which are still in effect. Even worst, the Court of Appeals' determination calls into question a state's legitimate police power to further health, safety, and welfare objectives.

Puerto Rico's health regulatory system, encouraged by the 1974 Act, established as one of its objectives the "present and projected need of the population," which included benefiting "unattended populations" (*i.e.*, low-income, disabled or elderly populations). The record before the Court of Appeals lacks sufficient evidence showing that Puerto Rico's CNC measure failed to suit this rationale. When the State is not a party to a contract, "courts ordinarily defer, within broad limits, to the legislature's judgment about the reasonableness and necessity of a particular measure." *See Energy Reserves Group, Inc. v. Kan Power & Light Co.*, 459 U.S. 400, 412-13 (1983). Such deference was warranted in the instant case.

ARGUMENT

In response to the 1974 Act, Puerto Rico enacted the Certificate of Necessity and Convenience Act of the Commonwealth of Puerto Rico (hereinafter "the CNC Act"), 1975 P.R. Laws 2 (codified as amended at 24 P.R. Laws Ann. §§ 334-334j), which required health service providers to show that their services were needed in a particular locale before they commenced servicing the area. In 1979, the CNC Act was amended in order to include pharmacies as "heath care facilities," which were also required to

satisfy this showing of need. Law No. 189 of July 29, 1979, amending 24 P.R. Laws Ann. §§ 334 et seq.

Under the CNC petition process, the Secretary of Puerto Rico's Health Department must consider the "present and projected need of the population" affected by the transaction, and the existence of alternatives to the transaction or the possibility of providing the proposed services in a more efficient or less costly manner." 24 P.R. Laws § 334b. Moreover, the Secretary must examine whether the proposed pharmacy will benefit "unattended populations" (*i.e.*, low-income, disabled or elderly populations), among other criteria. *See* Art. VI of Regulation 56 at Cert. Pet. App. 99 and Art. VII of Regulation 112 at Cert. Pet. App. 162.

As stated before, even though the statute's seasoned lifespan, on April 22, 2005, the Court of Appeals struck down the CNC Act understanding that it "impermissibly discriminat[ed] against interstate commerce." *Walgreen Co. v. Rullán*, 405 F.3d 50 (1st Cir. 2005). The basis for such determination was in essence the fact that the statute grandfathered the pharmacies which existed on October 24, 1979 in Puerto Rico, exempting them from the certificate requirement. 24 P.R. Laws Ann. at § 334g. However, the fact that twelve of Respondent's pharmacies benefited from such enactment went unnoticed by the Court of Appeals.[2] In addition, the Court of Appeals emphasized

---

[2] The District Court affording the appropriate weight to this consideration stated: "The fact that an overwhelming majority of the pharmacies in the island prior to 1979 were locally-owned, and this group was relieved from having to undergo the CNC application process, does not lead the Court to adduce a protectionist intent from the statute. In fact, at the time of the CNC amendment, Walgreens had twelve (12) pharmacies operating in Puerto Rico. Hence, this group of

(Continued on following page)

the fact that the statute authorized that, during a new pharmacy's CNC application process, the existing pharmacies within a one-mile radius of the projected area may file an opposition. *Walgreen Co.*, 405 F.3d at 57. Thereupon, the Court of Appeals engaged in an analysis of several statistics regarding the certificates' issuance purporting to show discrimination intent against interstate commerce – which were the same statistics that the District Court determined were "insufficient to establish a pattern of discrimination." *Walgreen v. Rullán*, 292 F. Supp. 2d 298, 315 (D.P.R. 2003).

APPLICABLE LAW: DORMANT COMMERCE CLAUSE

The Constitution provides that Congress shall have the power "to regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes." U.S. Const. art. I, § 8, cl. 3. The constitutional provision affirmatively granting Congress the authority to legislate in the area of interstate commerce "has long been understood, as well, to provide protection from state legislation inimical to the national commerce [even] where Congress has not acted." *Barclays Bank PLC v. Franchise Tax Bd. of Cal.*, 512 U.S. 298, 310 (1994), quoting *Southern*

Walgreens stores were also "grandfathered" – as coined by Plaintiffs – and automatically entitled to a CNC. When the CNC Act was amended to include pharmacies, the statute made no distinction between local and national pharmacies. On the contrary, the only distinction the statute makes among pharmacies are those established prior to and after October 24, 1979. In sum, Walgreens has not presented sufficient evidence to substantiate its conclusory allegation of discriminatory purpose. *Walgreen*, 292 F. Supp. 2d at 315. Cert. Pet. App. 44.

Pacific Co. v. Arizona ex rel. Sullivan, 325 U.S. 761, 769 (1945). This negative command, known as the dormant Commerce Clause, prohibits states from acting in a manner that burdens the flow of interstate commerce. *Okla. Tax Comm'n v. Jefferson Lines, Inc.*, 514 U.S. 175, 179-80 (1995); *Healy v. Beer Inst.*, 491 U.S. 324, 326 n. 1 (1989).

The restriction imposed on states by the dormant Commerce Clause is not absolute, and "the States retain authority under their general police powers to regulate matters of legitimate local concern, even though interstate commerce may be affected." *Maine v. Taylor*, 477 U.S. 131, 138 (1986). To determine whether a statute violates the dormant Commerce Clause, several levels of scrutiny apply, depending on the effect and reach of the legislation.

First, a state statute is a *per se* violation of the Commerce Clause when it has an "extraterritorial reach." *Healy*, 491 U.S. at 336. "[A] statute that directly controls commerce occurring wholly outside the boundaries of a State exceeds the inherent limits of the enacting State's authority and is invalid regardless of whether the statute's extraterritorial reach was intended by the legislature." *Id.* When a state statute regulates commerce wholly outside the state's borders or when the statute has a practical effect of controlling conduct outside of the state, the statute will be invalid under the dormant Commerce Clause. *Id.* A statute will have an extraterritorial reach if it "necessarily requires out-of-state commerce to be conducted according to in-state terms." *Id.*

Second, if a state statute discriminates against interstate commerce strict scrutiny should be applied. This means that the statute will be invalid unless the state can "show that it advances a legitimate local purpose that

cannot be adequately served by reasonable nondiscriminatory alternatives." *Or. Waste Sys., Inc. v. Dep't of Envtl. Quality of Or.*, 511 U.S. 93, 100-01 (1994) This level of scrutiny will be applied if the state statute discriminates against interstate commerce on its face or in practical effect. *Taylor*, 477 U.S. at 138; *see also Bacchus Imports, Ltd. v. Dias*, 468 U.S. 263, 270 (1984) (indicating that a finding of discriminatory purpose or discriminatory effect can constitute economic protectionism subjecting the state statute to a "stricter level of invalidity").

Third, a lower standard of scrutiny is applied when the state statute regulates evenhandedly and has only incidental effects on interstate commerce. In this situation, a balancing test is applied. *Pike*, 397 U.S. at 142. "Where the statute regulates evenhandedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits." *Id.* Moreover, the fact that a law may have 'devastating economic consequences' on a particular interstate firm is not sufficient to rise to a Commerce Clause burden. *See also Exxon Corp. v. Governor of Md.*, 437 U.S. 117, 127-28 (1978) (stating that "the [Commerce] Clause protects the interstate market, not particular interstate firms, from prohibitive or burdensome regulations.").

The proponent of a dormant Commerce Clause claim bears the burden of proof as to discrimination. *Immigration v. Enrico*, 533 U.S. 289, 300 n. 12 (2001); *Hughes v. Oklahoma*, 441 U.S. 322, 336 (1979); *Hunt v. Washington Apple Advertising Comm'n*, 432 U.S. 333, 353 (1977). This Court has established the elementary rule "that every reasonable construction must be resorted to in order to

save a statute from unconstitutionality." *Hooper v. California*, 155 U.S. 648, 657 (1895). To block summary judgment, the party having the burden of proof on a critical issue must present evidence on that issue that is "significantly probative," not "merely colorable." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249-50 (1986). In view of the Court of Appeals' statistical consideration at the case at bar, it must be noted also that "statistics are not irrefutable; they come in infinite variety and, like any other kind of evidence, they may be rebutted. In short, their usefulness depends an all of the surrounding circumstances." *International Bd. of Teamsters v. United States*, 431 U.S. 324, 340 (1977).

ANALYSIS

Asociación agrees with, and incorporates by reference, Petitioner's argument that the Court of Appeals failed to appropriately adjudicate within the dormant Commerce Clause doctrine the fact the Puerto Rico's CON program was established by invitation of the federal statute, the 1974 Act. Thus, the instant brief focuses on the Court of Appeals' misapplication of the level of scrutiny, which the case at bar deserved.

First, the Court of Appeals' strained look pointed to the fact that in 1979 "the Act, as amended, excused an almost entirely local class of pharmacies from the certificate requirement." *Walgreen Co.*, 405 F.3d at 55, Cert. Pet. App. 10. But this in itself fails to show a discriminatory intent on Puerto Rico's behalf. As stated in the petitioner's brief, this Court has consistently validated the inclusion of grandfather clauses within the regulatory schemes for the

issuance of certificates of necessity and convenience. *See Crescent Express Lines v. United States*, 49 F. Supp. 92, 94 (D.C.N.Y. 1943) (grandfather clause "was apparently inserted to avoid the hardship which would result from forcing a carrier to justify his existing business in terms of public convenience"), *aff'd*, 320 U.S. 401 (1943); *United States v. Carolina Freight Carriers Corp.*, 315 U.S. 475, 481 (1949) ("the purpose of the grandfather clause was to assure those to whom Congress had extended its benefits a substantial parity between future operations and prior bona fide operations"). This grandfather clause, standing alone, shows no other intent but for Puerto Rico's Legislature to establish a reasonable balance between the new regulating procedures and the already operating pharmacies, twelve of which pertained to respondents. In fact, at the time of the CNC amendment, Walgreens had twelve (12) pharmacies operating in Puerto Rico. As stated by the District Court, the fact that an overwhelming majority of the pharmacies in the island prior to 1979 were locally-owned, and this group was relieved from having to undergo the CNC application process, does not lead the Court to adduce a discriminatory or exclusionary intent. *Walgreen*, 292 F. Supp. 2d at 315. Cert. Pet. App. 44.

Second, the Court of Appeals found suspicious the fact that the statute authorized the existing pharmacies within a one-mile-radius to oppose a projected certificate petition. Again, the Court's taxing look is misplaced. According to the Court, "the Secretary invokes this authority [to deny a CNC] only upon the urging of a member of the largely local group of existing pharmacies, thereby permitting a predominantly local group to manipulate the regulatory scheme for its own advantage." *Walgreen*, 405 F.3d at 57. But this premise falls short of showing a discriminatory

animus. The fact that an opposing pharmacy is allowed to ventilate its disagreement at a petition process does not belie the Secretary's own prerogative to consider, grant or deny the petition. The record in this regard lacks any evidence to allow even the reference of such alleged manipulation.

Moreover, as stated by the petitioner, the one-mile requirement is a narrowly drawn measure, since it only allows that pharmacy which is established within the applicants' circumference. Thus, the one-mile requirement proscribes the "largely local group," to which the Court refers, from participating in the petition process.[3]

Third, the Court of Appeals determined that the statistical evidence strongly indicated discrimination, while the District Court concluded it was insufficient. In words of the District Court: "According to data provided by the Department of Health, the Secretary has granted ninety percent (90%) of local pharmacy petitions when opposed, and fifty-eight percent (58%) of mainland petitions when opposed." *Walgreen*, 292 F. Supp. 2d at 315. Both mainland and local pharmacies are granted petitions

---

[3] In this regard, the District Court held that: "Walgreens has not been denied access to the Puerto Rico market, except insofar as it seeks to establish new pharmacies in a one-mile radius where there are other existing pharmacies. More importantly, the statute applies equally to all potential pharmacies, regardless of their point of origin. Local pharmacy chains must face the same onerous procedure to obtain a CNC. The Act imposes the same burden on local pharmacy chains that seek to operate on the island. Therefore, the statute does not impose burdens on interstate commerce that exceed the burdens imposed on intrastate commerce." *Walgreen*, 292 F. Supp. 2d at 317. Cert. Pet. App. 49.

if they are unopposed. But most importantly, of the 58 CNC petitions submitted by Walgreen from 1979 to 2001, 43 were initially granted, and the 15 that were originally rejected were eventually granted as well.

The District Court correctly concluded that "Plaintiffs provide no information regarding the reasons for the denials of the out-of-state petitions vis a vis the local petitions. For example, certain petitions may have been denied because they were defective, or they sought the establishment of a pharmacy in a service area considered highly saturated pursuant to CNC guidelines. The Court is also unaware of the reasons why the CNC petitions granted to national pharmacies undergo a longer application process than those of local pharmacies. A myriad of factors might affect the application time-line. Such factors may include the service area where the pharmacy seeks to operate, the number of pharmacies already in the area, and the ratio of the area's population per pharmacy." *Walgreen*, 292 F. Supp. 2d at 315. Thus, as stated by this Court, statistics are refutable and subject to "all of the surrounding circumstances," which in this case were insufficient. *International Bd. of Teamsters v. United States*, 431 U.S. 324, 340 (1977).

Recently, the Court of Appeals in *Alliance of Automobile v. Gwadosky*, November 18, 2005, ___ F.3d ___, 2005 WL 3157574 (1st Cir. 2005), addressed again the dormant Commerce Clause doctrine. In this case, automobile manufacturers' association challenged the constitutionality of Maine statutory amendment prohibiting automobile manufacturers, already statutorily required to reimburse dealers at retail-repair rates for warranty repairs, from "otherwise recover[ing]" their costs of reimbursement, e.g., through state-specific wholesale vehicle surcharges. The

Court while upholding Maine's statute expressed the following: "Where, as here, a party presents circumstantial evidence of an allegedly discriminatory purpose in support of a dormant Commerce Clause argument, it is that party's responsibility to show the relationship between the proffered evidence and the challenged statute. . . . [quotations omitted] The record makes pellucid, however, that if a potential discriminatory purpose was lurking in the background, that purpose was, at most, incidental to the primary purposes that we have identified. Incidental purpose, like incidental effect, cannot suffice to trigger strict scrutiny under the dormant Commerce Clause." *Id.* at 7 (quoting *Pike*, 397 U.S. at 142).

As discussed previously, the findings before the Court do not show that the CNC Act bore disproportionately on out-of-state interests, and much less possessed so invidious an impact. A lower standard of scrutiny should have been applied, since the CNC statute regulates evenhandedly and has only incidental effects on interstate commerce. Respondents, as proponents of a Commerce Clause claim, failed to show the relationship between the proffered evidence and the challenged statute. Thus, a balancing test under *Pike* should have been applied.

"Where the statute regulates evenhandedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits." *Pike*, 397 U.S. at 142. Puerto Rico's health regulatory system, encouraged by the 1974 Act, established as one of its objectives the "present and projected need of the population," which included benefiting "unattended populations" (*i.e.*, low-income, disabled or elderly populations). Before the Court

of Appeals, there was no sufficient evidence showing that Puerto Rico's CNC measure failed to suit this rationale. When the State is not a party to a contract, courts ordinarily defer, within broad limits, to the legislature's judgment about the reasonableness and necessity of a particular measure. *See Energy Reserves Group, Inc. v. Kan Power & Light Co.*, 459 U.S. 400, 412-13 (1983). Such deference was warranted in the instant case.

CONCLUSION

Respondents failed to carry their burden of proof. The record is devoid of facts sufficient to allow the Court of Appeals to strike the CNC under the dormant Commerce Clause, under any of the scrutiny standards. The precedent set by the Court of Appeals places undue jeopardy on similar statutes intended to secure the health and proper health services to the community they intend to protect.

For the foregoing reasons, the petition for certiorari should be granted, and the judgment below reversed.

Respectfully submitted,

HARRY ANDUZE MONTAÑO
Counsel of Record
JOSE A. MORALES BOSCIO
1454 Ave. Fernández Juncos
San Juan, Puerto Rico 00908

No. 05-585

IN THE

Supreme Court of the United States

ROSA PEREZ-PERDOMO, in her official Capacity as Secretary of Health of the Commonwealth of Puerto Rico,
Petitioner,

v.

WALGREEN CO.; WALGREEN OF SAN PATRICIO; and WALGREEN OF PUERTO RICO,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the First Circuit

MOTION OF THE AMERICAN HEALTH PLANNING ASSOCIATION FOR LEAVE TO FILE A BRIEF AS *AMICUS CURIAE* IN SUPPORT OF THE PETITION FOR A WRIT OF CERTIORARI AND BRIEF OF THE AMERICAN HEALTH PLANNING ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF THE PETITION FOR A WRIT OF CERTIORARI

MARK S. JOFFE *
KELLI D. BACK
LAW OFFICES OF MARK S. JOFFE
1800 K Street, N.W.
Suite 720
Washington, D.C. 20006
(202) 457-6633

* Counsel of Record

December 8, 2005

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20001

IN THE

Supreme Court of the United States

No. 05-585

ROSA PEREZ-PERDOMO, in her official Capacity as Secretary of Health of the Commonwealth of Puerto Rico,
Petitioner,

v.

WALGREEN CO.; WALGREEN OF SAN PATRICIO; and WALGREEN OF PUERTO RICO,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the First Circuit

MOTION OF THE AMERICAN HEALTH PLANNING ASSOCIATION FOR LEAVE TO FILE A BRIEF AS *AMICUS CURIAE* IN SUPPORT OF THE PETITION FOR A WRIT OF CERTIORARI

The American Health Planning Association (AHPA) respectfully moves this Court for leave to file the accompanying brief *amicus curiae* in support of the *Petition for a Writ of Certiorari* submitted by Rosa Perez-Perdomo, in her official Capacity as Secretary of Health of the Commonwealth of Puerto Rico.

Respondents Walgreen Co.; Walgreen of San Patricio; and Walgreen of Puerto Rico refused to grant consent, offering no explanation, and necessitating this motion.

The interest of AHPA in this case stems from our knowledge and expertise in health planning, including state certificate of need programs, and our support for the important public policy objectives of state certificate of need programs to assure equitable access to health care at a reasonable cost for all persons. AHPA is the only national organization representing regional and state agencies engaged in the administration of state certificate of need programs.

AHPA and its members strongly support the use of certificate of need programs as an important health planning tool. Certificate of need programs are intended to promote a reasonable geographic distribution of health care services and facilities in order to avoid costs associated with excess health resource capacity while encouraging the development of needed health resources and services in medically underserved areas. Health planning in conjunction with certificate of need programs have the capability of improving both geographic and economic access to care.

For the above reasons, this motion for leave to file the attached brief *amicus curiae* should be granted.

Respectfully submitted,

MARK S. JOFFE *
KELLI D. BACK
LAW OFFICES OF MARK S. JOFFE
1800 K Street, N.W.
Suite 720
Washington, D.C. 20006
(202) 457-6633

* Counsel of Record

December 8, 2005

TABLE OF CONTENTS

TABLE OF AUTHORITIES

TABLE OF AUTHORITIES—Continued

IN THE

Supreme Court of the United States

No. 05-585

ROSA PEREZ-PERDOMO, in her official Capacity as Secretary of Health of the Commonwealth of Puerto Rico,
Petitioner,

v.

WALGREEN CO.; WALGREEN OF SAN PATRICIO; and WALGREEN OF PUERTO RICO,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the First Circuit

---

BRIEF OF THE AMERICAN HEALTH PLANNING ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF THE PETITION FOR A WRIT OF CERTIORARI

INTEREST OF THE *AMICUS CURIAE*

The American Health Planning Association (AHPA) is a national voluntary membership organization and non-profit public interest organization dedicated to the development of policies and community health systems that assure equitable access to health care at a reasonable cost for all persons.[1]

---

[1] Pursuant to Supreme Court Rule 37.6, *Amicus Curiae* states that no counsel for any party to this dispute authored the motion or brief in whole or part and no person or entity other than *Amicus Curiae* made a monetary contribution to the preparation or submission of the motion or brief.

AHPA is the only national organization representing regional and state agencies engaged in the administration of state certificate of need programs. AHPA members represent about one third of the states with certificate of need programs nationwide. AHPA's membership consists largely of representatives of state and regional planning and certificate of need agencies. AHPA is a nonprofit organization and is tax exempt under Section 501(c)(3) of the Code of the Internal Revenue Service.

AHPA's interest in this case stems from its concern that the ruling of the First Circuit Court could call into question states' authority to implement and enforce certificate of need laws that serve a valuable public policy purpose in controlling health care costs and ensuring appropriate access to quality services.

Community-based health resource planning and certificate of need regulation are flexible tools that can help states protect the critical health care infrastructure that is required to meet both expected and unanticipated public health care need. Certificate of need programs in conjunction with state and regional health plans can be and have been used to avoid unnecessary health care costs that are incurred when communities have excess health resource and service capacity. *See* Randall Bovbjerg, *Problems and Prospects for Health Planning: The Importance of Incentives, Standards, and Procedures in Certificate of Need*, 83 Utah L. Rev. 83, 85 (1978).

Health planning and certificate of need regulation are critically important tools available to states to promote and ensure that there is a reasonable geographic distribution of health care services and resources, including health services and resources needed in medically underserved areas. Certificate of need programs, in conjunction with state and community health plans, can be used, and often are used, proactively to improve both geographic and economic access to care.

In states without planning and certificate of need programs, communities and local jurisdictions are increasingly turning to local authorities and courts to try to compensate for the lack of planning and constructive regulation (application of state police power) at the state level. *See* Josh Duke, *Court Ruling Allows St. Francis to Resume its Plans to Build in Mooresville*, Indianapolis Star, November 4, 2005.

AHPA's concern is that the First Circuit Court's ruling may be used to undermine state certificate of need programs.

SUMMARY OF ARGUMENT

We urge the Court to grant certiorari in this case to avoid allowing the First Circuit Court's ruling to be used to undermine state certificate of need programs. Health planning and certificate of need regulation are critically important tools available to states to promote and ensure that there is a reasonable geographic distribution of health care services and resources, including health services and resources needed in medically underserved areas. Certificate of need laws also provide an important means by which states regulate the quality of health care services provided to their residents.

By their nature, certificate of need laws regulate the addition of health facilities, services and equipment to the market. Evaluating the market as it existed prior to enactment of the certificate of need program reflects the result of the unregulated market and does not provide insight into the impact of the law. Thus, the First Circuit should have limited its analysis of the Puerto Rico certificate of need law to the law's effect on the market after it was enacted.

If a law has the effect of discriminating against interstate commerce, the state must justify the law in terms of the local benefit flowing from the law and the unavailability of nondiscriminatory alternatives adequate to preserve the local interest at stake. *See Walgreen Co. v. Rullan*, 405 F.3d 50, 59

(1st Cir. 2005). AHPA believes, as discussed in this brief, that there are compelling policy reasons to support certificate of need programs, even if there were a disproportionate impact on interstate commerce.

ARGUMENT

I. THE VALUE OF CERTIFICATE OF NEED PROGRAMS

Certificate of need laws did not grow solely out of the Federal mandate set forth in the National Health Planning and Resources Development Act of 1974. *See* Pub. L. No. 93-641 88 Stat. 2225 (repealed 1986). Their development grew out of a clear, recognized need. Between 1966 and 1975, at least 29 states voluntarily implemented certificate of need laws before they were mandated nationally by the National Health Planning and Resources Development Act in 1976.[2] *See* American Health Planning Association, *National Directory of Health Planning, Policy and Regulatory Agencies*, January 2005.

Long before enactment of the National Health Planning and Resources Development Act, state enactment of certificate of need programs was recognized as a valid exercise of a state's police powers. *See Attoma v. State Department of Social Welfare*, 270 N.Y.S. 2d 167 (1966). Noting that the proliferation of nursing homes beyond the needs of a geographical area with spiraling cost to the users of such homes bears a reasonable relation to the welfare of the community, a court upheld one of the country's first certificate of need laws against constitutional challenge in 1966. *Id.* at 172.

In addition, a parallel program under Section 1122 of the Social Security Act (42 USC 1320a-1), which was enacted in

---

[2] As of 1975, the following states had certificate of need statutes: NY, RI, MD, CA, NJ, SC, WA,OK, NV, MN, ND, OR, AZ, MA, KY, MI, SD, KS, CT, FL, TN, VA, IL, HI, OH, AR, MT, TX and CO.

1972 and therefore preceded enactment of the National Health Planning and Resources Development Act, was intended to assure that Medicare and Medicaid funds were not used to support unnecessary capital expenditures and that reimbursement under Medicare and Medicaid would support health planning activities in the states. Section 1122 granted states the authority to deny Medicare, Medicaid, and Title V (Maternal and Child Health Program) reimbursement to facilities whose capital expenditures were not approved by a state health planning agency.

While a handful of states repealed their certificate of need laws after Congress repealed the National Health Planning and Resources Development Act in 1986, most states retained the laws in recognition of the value of health planning. Moreover, in response to the rapid escalation of cost and loss of access of care, in the early 1990s some states that had abandoned health planning in whole or part passed new certificate of need laws. *See* Robert Pear, *States are Moving to Re-Regulation on Health Costs: Planning is Back in Favor*, New York Times, at 1 (May 11, 1992).

Recent changes in the hospital market may make certificate of need laws even more valuable. A recent article in *Health Affairs* states that market driven health care environments are endangering the financial viability of community hospitals by allowing for the proliferation of physician owned specialty hospitals. *See* Sujit Choudhry, Niteesh K. Choudhry, and Troyen A. Brennan, *Specialty Versus Community Hospitals: What Role For The Law?*, Health Affairs Web Exclusive, 9 Aug 2005, http://content.healthaffairs.org/cgi/reprint/hlthaff.w5.361v1.pdf.

The authors concluded that state certificate of need laws are the best solution to ease the burden to community hospitals and ensure access to care without stifling innovation and efficiency. *Id.* at W5-367.

Certificate of need laws also provide an important means by which states regulate the quality of health care services provided to their residents. The most recent and largest study of certificate of need regulation on treatment outcomes found that open heart surgery mortality rates are more than 20 percent lower in states with certificate of need regulation than in states without regional planning and regulation. *See* Mary S. Vaughan-Sarrazin, PhD; Edward L. Hannan, PhD; Carol J. Gormley, MA; Gary E. Rosenthal, MD, *Mortality in Medicare Beneficiaries Following Coronary Artery Bypass Graft Surgery in States With and Without Certificate of Need Regulation*, J. Am Med. Ass'n, Vol. 288 No. 15, October 16, 2002, 1859-1866.

In addition, empirical studies by all three major U.S. automakers show substantially lower health care costs in states with certificate of need programs. *See* General Motors Corporation, *Statement of General Motors Corporation on the Certificate of Need (CON) Program in Michigan*, February 12, 2002; Ford Motor Company, *Relative Cost Data vs Certificate of Need (CON) for States in Which Ford has a Major Presence*, February 2002; DaimlerChrysler Corporation, *Certificate of Need: Endorsement by DaimlerChrysler Corporation*, February 2002.

II. THE FIRST CIRCUIT ERRED IN TAKING INTO CONSIDERATION THE COMPOSITION OF THE PHARMACY MARKET PRIOR TO ENACTMENT OF PR LAW 189

The dormant Commerce Clause is not absolute in its restriction on the states, and in the absence of conflicting legislation by Congress, "the States retain authority under their general police powers to regulate matters of legitimate local concern, even though interstate commerce may be affected." *Pharmaceutical Care Management Association v. Rowe*, 2005 WL 2981063 (1st Cir.(Me.)) *quoting Maine v.*

Taylor, 477 U.S. 131, 138, 106 S. Ct. 2440, 91 L.Ed.2d 110 (1986).

A key finding of the First Circuit's Court's decision was that the Puerto Rico certificate of need law discriminated against out-of-state pharmacies because pharmacies existing prior to 1999 did not have to obtain a certificate of need and most existing pharmacies were locally owned or controlled. *Walgreen*, 405 F.3d at 58. AHPA questions the validity of this factor in the First Circuit's analysis of the Puerto Rico certificate of need law.

Certificate of need laws, by their nature, regulate the addition of health facilities, services and equipment to the market. *See* Patrick John McGinley, *Beyond Health Care Reform: Reconsidering Certificate of Need Laws in a Managed Competition System*, 23 Fla. St. U. L. Rev. 141, 144 (1995). They are not aimed at regulating the market as it exists at the time of enactment. Thus, grandfathering existing services is an inherent part of a certificate of need program. An examination of the certificate of need requirements of the National Health Planning and Resources Development Act reinforces this position. That law created two regulatory schemes—certificate of need programs for new projects and appropriateness review for existing facilities and equipment. *See* Pub. L. No. 93-641, 88 Stat. 2225, Sections 1523(a)(4) and (a)(5) of the Public Health Service Act (repealed 1986).

With no evidence of discriminatory intent, evaluating the market as it existed prior to enactment of the certificate of need program does not provide insight with respect to the impact of the law. In fact, it reflects the result of the unregulated market. Thus, the fact that local interests may have dominated the pre-existing market should not be relevant to this analysis.

The First Circuit Court also noted that the Puerto Rico law is protectionist both *de jure* and *de facto* because it directs the

Secretary to reject a new pharmacy's request if the proposed location is already saturated with existing pharmacies. *Walgreen*, 405 F.3d at 56. This is precisely the intent of certificate of need laws, which is to avoid unnecessary duplication of health services in order to keep costs low.

The First Circuit applied the legal principle that, if a law has the effect of discriminating against interstate commerce, the state must justify the law in terms of the local benefit flowing from the law and the unavailability of nondiscriminatory alternatives adequate to preserve the local interest at stake. *Walgreen*, 405 F.3d at 59. The First Circuit erred, however, in applying the principle. AHPA believes that there are compelling policy reasons to support certificate of need programs, even if there is a disproportionate impact on interstate interests.

Moreover, in light of the fact that the Puerto Rico law treats all pharmacies applying for certificates of need alike, AHPA would urge application of the tests set forth by the Supreme Court in *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 90 S.Ct. 844, 25 L.Ed.2d 174 (1970). In that case, the Court held that "Where the statute regulates evenhandedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits." *Id.* at 142.

As previously noted, health planning and certificate of need regulation are critically important tools available to states to promote and ensure that there is a reasonable geographic distribution of health care services and resources, including health services and resources needed in medically underserved areas. Recognizing the value of these tools, a majority of states established certificate of need programs well before there was a congressional mandate to do so, and thirty-six states, the District of Columbia, Puerto Rico, and the U. S. Virgin Islands continue to rely on them. Certificate

of need programs, in conjunction with state and community health plans, can be used, and often are used, proactively to improve both geographic and economic access to care.

CONCLUSION

This court should grant the petition for certiorari and reverse the First Circuit's decision.

Respectfully submitted,

MARK S. JOFFE *
KELLI D. BACK
LAW OFFICES OF MARK S. JOFFE
1800 K Street, N.W.
Suite 720
Washington, D.C. 20006
(202) 457-6633

* Counsel of Record

December 8, 2005